

LESSONS LEARNED FROM IMPLEMENTING PROJECT LAZARUS IN NORTH CAROLINA

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention, the Kate B. Reynolds Charitable Trust, or the North Carolina Office of Rural Health. This white paper is based on webinars which summarize the lessons we learned from implementing Project Lazarus.

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SYNOPSIS

On May 11, 2015 and June 29, 2015, the Injury Prevention Research Center (IPRC) of the University of North Carolina at Chapel Hill (UNC-CH) presented two webinars on the lessons learned from implementing Project Lazarus in North Carolina (NC). The webinars were hosted through the generous services of the Children's Safety Network. The broadcasts were funded through grants from the Centers for Disease Control and Prevention (CDC), the Kate B. Reynolds Charitable Trust (the Trust), and the North Carolina Office of Rural Health and Community Care (the Office). The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of CDC, the Trust, or the Office. This white paper, which is organized by the content of these webinars, summarizes the lessons learned.

Project Lazarus is a community-based initiative developed to reduce the epidemic of opioid-related overdoses, abuse, and diversion. The project encompasses a hub and seven spokes. The hub comprises three components, namely 1) public awareness of the problem of overdose from prescription opioid analgesics, 2) local coalition action to coordinate all sectors of the community's response, and 3) data and evaluation to ground the community's approach in its locally identified needs, and to improve interventions. The spokes represent 1) community education to improve the public's capacity to recognize and avoid the dangers of the abuse of prescription opioids, 2) provider education to support screening and appropriate treatment for mental illness, addiction and pain, 3) hospital ED policies to help providers recognize and respond appropriate to patients' drug-seeking behavior, 4) diversion control to reduce the presence of unused controlled substances, 5) pain patient support to help patients and caregivers manage chronic pain, 6) harm reduction to help prevent opioid overdose deaths by means of the antidote naloxone, and 7) addiction treatment to help find effective treatment for patients ready to enter recovery. The key lessons learned, as summarized below, are pertinent to each of the components of the hub and the wheel's spokes.

Lessons Learned from the Hub of the Project Lazarus Model

Public Awareness

- Neither individuals nor organizations can make wise decisions to bring about a change in beliefs, behavior, or practice without actively educating a community about the potentially dangerous outcomes associated with using prescribed opioid analgesics as a pain management tool.

- Stakeholders are busy people who should be engaged to better understand the essence of the problem, gain buy-in of the model, and agree in principle about what the solutions could be. Effective community-based overdose prevention coalitions are supported by a constellation of leadership, community champions, and interested community members who have the time required to receive training, build community consensus, and to develop strategies and detailed action plans.
- Every community in North Carolina is different, ranging from sprawling urban cities to tight-knit rural towns in the mountains and along the coast, from US military bases to American Indian reservations. Each comes with its own built-in prejudices, biases, and belief systems. And as every community is ultimately responsible for its own health, its response to the epidemic of overdose deaths from prescribed pain medication, and to the increasing prevalence of substance use disorders among the citizens, will equally be unique.

Coalition Action

- The portal of entry for forming community-based overdose prevention coalitions is different in each community, and finding one entity to establish the infrastructure statewide has not worked.
- A community-based overdose prevention coalition is not intended to be just another service agency; nor should it be convened to support the work of an extant agency. Instead, it should serve as a catalyst and advocacy group for policy and social change by targeting beliefs and perceptions, raising community awareness, and changing rules, regulations, policies, and practices in the community.
- Rural communities typically have fewer resources, training opportunities, and support systems to start and sustain a community-based overdose prevention coalition. They have a greater need for training around policy, environmental, and system change as they are often more comfortable with developing programs and services targeted at the individual, as opposed to the community.
- Identifying and engaging members of the community who have shown leadership skills in areas other than overdose prevention is critical in selecting those who can lead, promote, and sustain the coalition's efforts.

- It may be more productive and sustaining for leadership roles on an overdose prevention coalition to change periodically and last for shorter amounts of time, such as for one project goal at a time, and not for the duration of the coalition.
- Coalitions can gain stability and make progress when goals and strategic plans are clearly established, even during times of sparse funding, by co-opting funding for similar or shared missions and plans of other local organizations.
- Coalitions that embrace the role of change agent, in contrast to that of a service agency, can often sustain their effectiveness in periods of diminished funding by availing themselves of educational materials and technical expertise provided by Project Lazarus, and by institutionalizing overdose prevention strategies in other local organizations and agencies with similar missions related to preventing overdoses from prescription medication and other drugs.

Data and Evaluation

- All public health initiatives, especially new overdose prevention programs, benefit from outcome and process program evaluations. These evaluations will ideally draw data from multiple sources. The type and degree of evaluation should reflect program needs and a clear appreciation of the limits of the data on which the evaluation is based.
- Hospital data are becoming readily available and can be used for overdose surveillance for outcome data; however, due to considerable variation across hospitals in coding overdose-related encounters and limited specificity in identifying opioids, findings should be interpreted with caution.
- Although reductions in overdose mortality is often considered the most important outcome by which funding agencies track program success, the number of deaths by county, over time, often lack adequate statistical power to provide highly detailed feedback. Nevertheless, mortality data can be aggregated to the state level for a full year to be meaningful.
- While data from PMPs are detailed and informative, the databases are enormous, require extensive cleaning and analysis, and are limited and do not provide information about what medical condition prompted the opioid prescription.
- Process evaluation data are often collected for grant reporting, which may introduce over-reporting bias if the reporter seeks to reassure the funder that all promised activities were implemented as intended.

- Securing a full and timely response to surveys requires considerable follow-up and adds to costs and to study personnel time.
- Keeping abreast of the methodological changes in each data source gives confidence to the agency responsible for collecting the data that it will be used responsibly. This may include paying attention to funding decisions by the state legislature and personnel changes within health departments.
- The more the study's methodology is presented, the clearer the message becomes. Plans for the study design must be run by wide types of audiences and stakeholders at different levels of scientific aptitude.
- Writing the methods section for a publication is much easier when the author does the data cleaning.

Lessons Learned from the Spokes of the Project Lazarus Model

Community Education and Pain Patient Support

- Meeting a community's needs and bringing about the desired change that addresses the epidemic caused by prescribed pain medications requires a balanced and comprehensive approach.
- Engaging the general public requires connecting the dots in their lives to show why they need to be engaged. Three basic questions need to be posed: (1) Why am I needed? (2) What do I need to know? (3) What needs to be done?
- Statistics often need to be translated and their relevance should be communicated for the general public within every segment of a community.
- No one optimal rate for overdose mortality or opioid prescribing exists. Every community is different.
- The biggest obstacle to reaching those who need help and care by changing community norms is counteracting the myths that result in stigmas and prejudices.
- The availability of entrenched leadership willing to promote Project Lazarus, rather than the rate of overdose mortality within the community, was the most effective predictor of implementation success and sustainability.
- A support network for those with chronic pain is sorely lacking within almost every community.

- Integrating behavioral health into general primary care services often compensates for lack of resources and referral mechanisms available in most communities.
- It takes a local spokesperson who has lived with chronic pain and uses a peer-to-peer approach, bring the right people together.

Provider Education and Hospital Emergency Department Policies

- Previous experience has shown that to be effective, behavior change, including prescribing opioids, is extraordinarily difficult and requires technical assistance including mentoring, skills development, and, most of all, systems redesign.
- The cognitive buy-in to the principles of Project Lazarus was not difficult. The challenge was getting the right people to the table and implementing the required practice changes.
- Many practitioners are unaware of the availability of behavioral health and substance use disorder resources in their own communities. Accessing and using these resources needed to be reinforced as part of the case studies, discussions, and didactic material presented during each training.
- Educational content about safely and appropriately prescribing opioid analgesics should be framed so practitioners are not unintentionally deterred from prescribing any opioid-based medications.
- The curriculum needs to be continually modified to reflect evolving best practices, in spite of the general appeal of continuity and consistency of its use over even a relatively short (2 year) period.
- Changing the clinical practice culture of pain management in emergency departments was more difficult than anticipated. The “bottom-up” advocacy of the leadership of community overdose prevention coalitions had more impact than the “top-down” educational training offered.
- EDs are neither appropriate nor equipped for relatively complicated pain and behavioral health assessments or treatment.

Harm Reduction

- Two crossover populations have harm reduction and medical model overdose prevention programs in common: people who use pharmaceutically manufactured opioids obtained from both licit and illicit sources, and people who are potential witnesses to an opioid overdose who could be trained to recognize and reverse it using rescue breathing and naloxone.

- Few significant changes in most aspects of overdose prevention begin without legislative sanctions. There is never a bad time to seek the passage of enabling legislation, regardless of the political persuasion of the legislature.
- Practitioners should not assume that a new naloxone provider or user will only be willing to use one type of delivery system. All options should be discussed.
- Within North Carolina and across the country, documenting the distribution of naloxone, the number of reversals, and the collaborative work that fosters community-based distribution continues to be challenging.
- Users are less likely to call a phone number or visit a Web address to report reversals even if they are prominently listed on the kit.
- Making oft-held assumption that law enforcement is an unwilling partner in overdose prevention and harm reduction can be dangerous.

Diversion Control

- Partnering with local agencies, such as Project Lazarus, Community Care of North Carolina and the Injury Branch of the Division of Public Health that have similar goals can compensate for less than optimal staffing within law enforcement and has extended the State Bureau of Investigation's Diversion Unit's capacity to address illicit controlled substances within the state.
- Building community awareness of the dangers of the misuse and abuse of prescription pain medication can gain additional credence and community buy-in when presented by law enforcement.
- Using the positive experiences of law enforcement from other states in community-based distribution of naloxone was a critical component in convincing the local administration to allow unit officers to carry naloxone.
- The DEA would have stopped sponsoring Pill Take-Back Days as of fall 2015 were it not for intense national community advocacy for continued support.

Addiction Treatment

- Engaging and retaining patients with addiction in treatment, rather than a punitive approach of discharge, is an important practice in overdose prevention.
- Many practitioners may be reluctant to screen for indices of substance use disorder(s) using the SBIRT model when treating pain patients with opioid analgesics. Their reluctance in referring

patients found at risk of an overdose is often based on their inability to identify local and affordable resources for behavioral health management and substance use disorder treatment.

- Focusing on system wide change in major health systems that employ several physicians is more cost effective than working with individual physicians.
- The inadequate supply of providers licensed to prescribe buprenorphine for Medicaid patients is frequently not due to the 30 eligible patients/100 patient limit, but to the billing preferences of its providers that only accept fee-for-service, i.e., cash-only patients, or those with commercial insurance.
- Integrating co-prescriptions of naloxone and opioid analgesics into the clinical practice of pain management is more difficult than community based distribution of naxolone to active opioid users and to those who may witness an overdose, such as family members, first responders, and law enforcement officers.

LESSONS LEARNED FROM IMPLEMENTING PROJECT LAZARUS IN NORTH CAROLINA

Introduction

History

On May 11, 2015 and June 29, 2015, the Injury Prevention Research Center (IPRC) of the University of North Carolina at Chapel Hill (UNC-CH) presented two webinars on the lessons learned from implementing Project Lazarus in North Carolina. The Children's Safety Network hosted the webinars and The Centers for Disease Control and Prevention (CDC), the Kate B. Reynolds Charitable Trust (the Trust), and the North Carolina Office of Rural Health and Community Care (the Office) provided grants to fund the broadcasts. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of CDC, the Trust, or the Office. The following is a summary of the presentations that were a key part of these webinars.

In 2002, the Injury Prevention Branch of the North Carolina Division of Public Health (DPH) identified evolving patterns of unintentional poisonings in NC. The Injury Prevention Branch requested an epidemic intelligence service investigation from CDC. In response, a 25-member task force was established to provide the NC Secretary of Health and Human Services with recommendations for the state's epidemic of unintentional drug overdoses from prescription pain medication. The development of community-based overdose prevention programs was among the more than 50 recommendations in the Task Force's report presented to the Secretary.

In 2004, Hospice programs in Wilkes County (a rural county in the foothills of the Appalachian Mountains in the western part of the state) informed their chaplain, Fred Wells Brason II, that prescribing opioid pain medication to terminally ill cancer patients under their care may need to be discontinued because of the sudden increase in the misuse and diversion of these opioids w by these patients or their family members. Chaplain Brason who serves as the chair of the county's Healthy Carolinians Substance Abuse Task Force, sought answers from the county's health department, medical care providers, and law enforcement officers. Over time, the Wilkes County Health Department, the county Medicaid services office, and the sheriff's department made overdose prevention and opioid diversion control a priority. By the end of 2007, Chaplain Brason and colleagues had designed Project Lazarus, a community-based drug overdose prevention program focused on reducing fatal overdoses from prescription pain medication. The program is designed to identify and integrate community awareness and coalition building activities with evidence-based or promising overdose prevention

strategies.¹ From the outset, the underlying premise of Project Lazarus was that each community should ultimately be responsible for its own health. Furthermore, with a minimal amount of training and outside support, individual communities could develop sustainable infrastructure and select interventions that resonate with and are appropriate for those who are most affected by the use, misuse, and abuse of prescription pain medication. The ultimate goal of Project Lazarus is to decrease deaths from opioid-related overdoses, promote appropriate care for patients with chronic pain, and to enhance local services that offer treatment for substance use disorders.

The Project Lazarus Model

The Project Lazarus Model can be conceptualized as a wheel with a hub and seven spokes as depicted in Figure 1. The hub, which represents various community-based, bottom-up activities, contains four key activities:

1. Enhancing public awareness of the need to take action to prevent overdoses,
2. Developing effective community-based coalitions to implement drug overdose prevention strategies that will meet the community's needs,
3. Using data to demonstrate the nature of these needs, and
4. Applying program evaluation to determine the extent to which the actions adopted and implemented are successful.

In many cases, hub-related activities include the community education spoke. This spoke is designed not only to raise the public's awareness of and sensitivity to substance use disorders, but also to provide information about how community members can be proactively engaged in addressing the often unintentional adverse consequences of prescribing and using opioid analgesics and other controlled substances that can lead to misuse, abuse, addiction, or death.

¹ See www.projectlazarus.org



Figure 1: The Project Lazarus Model, Hub, and Spokes

The spokes of the Project Lazarus model (often referred to as its top-down components) include a menu of “evidence-based,” “innovative,” or “best practices” for mitigating the unintended adverse consequences of using prescribed opioid analgesics, from which communities can choose. Some of these interventions target medical providers, such as for adopting guidelines for appropriate opioid analgesic prescribing practices, and for emphasizing the importance of registering with and using NC’s prescription drug monitoring program, the Controlled Substances Reporting System (CSRS). A related spoke also targets the medical care profession, by recommending changes to opioid prescription policies in hospital emergency departments (EDs) and other urgent care facilities. Another spoke, which describes the law enforcement and diversion intervention, communicates to law enforcement that the diversion of prescribed opioid analgesics should be approached as a public and mental health problem, and not a criminal one. This intervention is often implemented in collaboration with community organizations to decrease the availability of diverted prescription medications by facilitating their proper disposal at “drug take-back” events, or in medication drop boxes located throughout the community. Several spokes describing patient support and substance use disorder treatment involve advocating and providing treatments that do not rely on prescribing pain medication to patients with chronic pain, and

promoting available and accessible substance use disorder treatment to those who may acquire a substance use disorder. The final spoke, harm reduction, focuses on strategies that reverse potentially life-threatening overdoses prior to the arrival of professional medical care. Together, these harm reduction strategies involve all members of a community and include changing cultural norms, developing legislative policies, and training medical care providers, pharmacists, law enforcement officers, first responders, and those who are likely to witness an opioid overdose to administer naloxone—a “rescue” medication that immediately reverses the effects of an opioid overdose.

Development of Project Lazarus

Project Lazarus was introduced in Wilkes County in 2008. Within 2 years, every medical care provider in the county who prescribed opioid pain medications had been trained by the medical director of the county’s health department using the Project Lazarus Medical Care Provider Toolkit. This toolkit was prepared jointly by Project Lazarus and the Northwest Community Care Network, which subsequently became the Community Care of North Carolina’s Chronic Pain Initiative (CPI) Medical Care Provider Tool Kit.² By 2011, the Wilkes’ County mortality rate of overdoses from opioid pain medications declined by 69 percent. All fatal overdoses during this time were coded as accidental poisonings from prescription opioids; none resulted from heroin overdoses. Medical care providers who practiced in Wilkes County also changed their opioid pain medication prescribing behaviors. In contrast to earlier years, none of the decedents from a fatal overdose involving an opioid in 2011 obtained the prescription for the pain medication responsible for the death, from a medical care provider practicing in Wilkes County. Though the county’s opioid pain medication prescribing rate continued to exceed the state’s average (as depicted in Figure 2), the rate by 2011 had stabilized, which shows that the right people continued to receive the pain medication that their medical care providers believed they needed.

² Available at [http://www.wilkescounty.org/health/behavioral-health/](#)

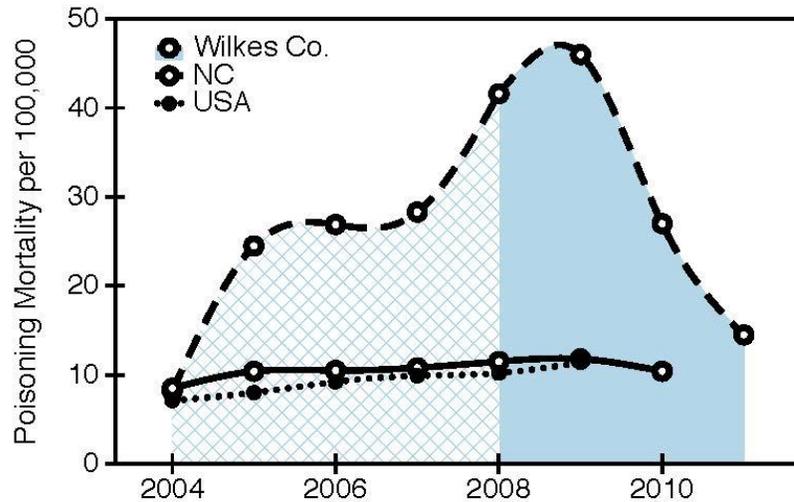


Figure 2: Poisoning Mortality Rate in Wilkes County, NC and in the United States

Project Expansion

By 2011, the success of Project Lazarus in Wilkes County served as a major catalyst to implement the program in NC's other 99 counties, the Cherokee Nation, and the US Army's Wounded Warrior Program at Fort Bragg. However, moving from a single county-based drug overdose prevention program to a statewide endeavor required considerable support. When Project Lazarus was first implemented in the US Army and the Cherokee Nation, additional resources were necessary to expand the program to the state's other 99 counties. Four major players emerged to support this expansion. The Trust and the Office jointly contributed \$2.6 million to implement the hub and spoke activities of the Project Lazarus model, which was sufficient to introduce or support Project Lazarus activities in all 100 NC counties. Community Care of North Carolina (CCNC), the state's Medicaid authority, provided the clinical and administrative infrastructure to implement Project Lazarus in the State's 14 Medicaid networks, which offer a clinical infrastructure to providers who treat the medically indigent across the entire state. CDC also funded IPRC at UNC-CH to evaluate the effects of the statewide rollout of Project Lazarus.

The Kate B. Reynolds Charitable Trust is a nearly 70 year-old private foundation dedicated to improving the health and quality of life for financially disadvantaged residents in NC. As one of the state's leading private health funders, 75 percent of its annual grant making is focused on improving health and health care statewide, particularly in the state's most socioeconomically disadvantaged counties. For the past decade, Trust funding has been focused on access to care, behavioral health, and diabetes. By 2011, prescription drug abuse had become an emerging area of concern. Allen Smart, Director of Programs, and Nora Ferrell, Director of Communications, indicated that a primary reason the

Trust invested in the expansion of Project Lazarus throughout the state was due to the Trust's increasing concern about the misuse and abuse of prescription pain medication. The alignment of Project Lazarus' model with the Trust's policies helped coordinate the activities of several of the existing health care systems within the state, such as CCNC, the CSRS, and state hospital EDs. According to Nora Ferrell, "The results were stunning." By 2011, Wilkes County had experienced a 69 percent drop in the overdose death rate, a 15.3 percent reduction of substance abuse-related ED admissions, and a significant increase in the number of medical care providers who had registered with the CSRS (i.e., more than 70 percent of Wilkes County prescribers had registered with the CSRS versus a statewide average of 26 percent).

The Office of Rural Health and Community Care became a co-sponsor of the rollout of Project Lazarus to all 100 counties in NC, matching the Trust's funding dollar for dollar. The office was created in 1973 within the NC Department of Health and Human Services (DHHS). At its inception, it was charged with assisting underserved communities by creating and supporting a network of rural health centers across the state. Since then, the office has expanded its mandate to empowering communities and populations by developing and/or supporting innovative strategies to improve access to, and the quality and cost-effectiveness of, health care for all NC residents. Trust funding supports the implementation of Project Lazarus in approximately 30 of the state's most economically disadvantaged counties; the office covers the residual at about 40 percent of the per-county dollars provided by the Trust.

The Importance of Collaboration

CCNC created and profited from the input of its Project Lazarus Advisory Board, comprised of volunteer stakeholders interested and involved in the complex aspects of preventing opioid overdoses in NC. The board initially met monthly (in year 1) and then bimonthly (in subsequent years) to review concerns and lessons learned. Members include primary care, behavioral health and pain management providers, professional societies (i.e., medical, dental), professional boards (i.e., medical, dental, and pharmacy), state agencies (i.e., Division of Mental Assistance, Division of Mental Health, Division of Public Health), the North Carolina Community Health Center Association (FQHCs), CSRS, North Carolina Area Health Education Centers (AHEC), the North Carolina Hospital Association, law enforcement, and Pfizer, a pharmaceutical company. During the second Project Lazarus Lessons Learned webinar, presenter Dr. Sara McEwen, the executive director of the Governor's Institute on Substance Abuse in NC, and director of the clinical education component of the Project Lazarus model, indicated that the diverse composition of the Advisory Board was pivotal to the success of introducing Project Lazarus across the state. Specifically, the collaborative nature of the Board aided in recruiting participants for

the 40 chronic pain initiative educational programs presented throughout the state during the first 2 years of the Project Lazarus rollout.

Although a casual read of this paper will result in a compendium of many of the intervention strategies recommended by the Project Lazarus model, the goal is to describe the lessons learned by key stakeholders who have been and are involved in implementing representative intervention strategies. Insights gained by these presenters can be applied in other contexts, thus reducing the time and cost of implementing Project Lazarus or a comparable community-based overdose prevention program focused on mitigating the adverse consequences inherent in prescribing opioid-based pain medications.

Program Evaluation

Program evaluation is an explicit component of the Project Lazarus model and includes continuous community- and coalition-level process assessments during the implementation of the model. It also includes outcome assessments at the end of implementation of the interventions that are selected to prevent drug overdoses. CDC identified Project Lazarus as a candidate for a best practices model for prescription drug overdose prevention and funded IPRC at UNC-CH to serve as an independent program evaluator. IPRC has evaluated several programs associated with drug overdose prevention programs within the state, and two of its research staff had been involved in the conceptual design of Project Lazarus. CDC funded IPRC to encourage research to build the scientific base for preventing drug overdoses in the adolescent and adult population in the United States. The effectiveness study awarded to IPRC will test whether the statewide community-based initiative (1) increased providers' rates of registry and consultation with the state's prescription monitoring program, (2) improved access to substance abuse treatment by increasing the number of individuals who receive medically-assisted treatment for opioid dependence, and (3) decreased drug-related morbidity and mortality rates attributable to opioid overdoses. These rigorous epidemiological evaluation strategies of Project Lazarus are aligned with previous initiatives funded by CDC, and build upon advances in the field.

Research to Practice

As drug overdose prevention programs move from research to practice, Dr. Karin Mack, a CDC scientific advisor, underscored the critical nature of understanding the feedback loops necessary to create efficiencies and to achieve the greatest public health benefit. Dr. Mack articulated that lessons learned is a principal component of continuous improvement and indicated that one need not wait for post-implementation analyses to determine the value of a public health intervention. And while a lesson learned can be as simple as asking, "What worked well or what did not work so well?", capturing and disseminating lessons learned are critical for emerging fields, particularly when the information gained is

used to establish or improve programs that save lives. Dr. Mack concluded that the depth and breadth of the knowledge gained from Project Lazarus should prove useful as a launching point for future community-based drug overdose prevention work.

It was clear from the outset that the rollout of Project Lazarus from Wilkes County to the rest of the state would require a formal administrative infrastructure considerably more robust than the program management capacity of the program operating in the county, the Cherokee Nation, and at Fort Bragg. The Project Lazarus model is based on traditional community-based public health and mental health top-down and bottom-up principles; the hub components of the model are best handled at the community level, primarily through county-based drug overdose prevention community coalitions. The spoke components of evidence-based or best practice interventions are designed to reach the state's providers of medical and mental health care and law enforcement.

Few programs in NC have entered into the clinical practices of as many medical care providers and patients as the state's Medicaid authority, CCNC. Similar to the philosophy of Project Lazarus, the underlying principle of CCNC is that the best medical care systems are rooted in the community they serve. CCNC collaborates with clinical care and social service agencies and other community-based organizations to provide cooperative and coordinated care, which ultimately improves the efficiency of health care services. Almost 10 million residents live in NC. CCNC serves the state's Medicaid-eligible population of 1.4 million enrollees through 4,600 physicians grouped in more than 1,600 primary care practices in 14 administrative networks, as illustrated on the adjacent map. Some of these networks are composed of only one county, while several cover more than 20 counties (Figure 3). Funders and providers recognized that there could not be a one-size-fits-all approach. The strategies that worked in one CCNC network might not work in another. Nevertheless, there was a general understanding that the lessons learned from each network might help the others.



- Legend**
- ◆ AccessCare Network Sites
 - AccessCare Network Counties
 - Community Care of Western North Carolina
 - Community Care of the Lower Cape Fear
 - Carolina Collaborative Community Care
 - Community Care of Wake and Johnston Counties
 - Community Care Partners of Greater Mecklenburg
 - Carolina Community Health Partnership
 - Community Care Plan of Eastern Carolina
 - Community Health Partners
 - Northern Piedmont Community Care
 - Northwest Community Care
 - Partnership for Community Care
 - Community Care of the Sandhills
 - Community Care of Southern Piedmont

Figure 3: Community Care of North Carolina Regional Network Map

Part 1: Implementing Project Lazarus in North Carolina: Lessons Learned from the Project Lazarus Model

The Community-based (“Bottom-up”) Components of the Project Lazarus Model: Public Awareness

Fred Wells Brason, II, chaplain and Project Lazarus CEO, describes the Public Awareness element in the hub of the Project Lazarus Model. This element most closely corresponds to the first of the hub’s four activities, enhancing public awareness of the need for action to prevent overdoses.

As early as 2004, long before the design of Project Lazarus was complete, local law enforcement, EDs, and the Hospice agencies in Wilkes County, NC, were fully aware that there were problems with the opioid analgesics prescribed for pain management to community members suffering from chronic or terminal cancer. Prior to 2007, several Project Lazarus co-founders, supported by the advocacy of the county’s Public Health Director, identified local stakeholders and began to present data reflecting the county’s excessively high fatal overdose rates, high use of the local EDs for overdose-related treatment, and prescriptions for opioid pain medicine profiles that were well above the state average. However, it took a sensationalized newspaper article about three fatal overdoses that occurred within 48 hours to effectively gain the community’s attention that led to the creation of an active community-based overdose prevention coalition.

LESSON LEARNED: Neither individuals nor organizations can make wise decisions to bring about a change in beliefs, behavior, or practice without actively educating a community about the potentially dangerous outcomes associated with using prescribed opioid analgesics as a pain management tool.

LESSON LEARNED: Stakeholders are busy people who should be engaged to better understand the essence of the problem, gain buy-in of the model, and to agree in principle about what the solutions could be. Effective community-based overdose prevention coalitions are supported by a constellation of leadership, community champions, and interested community members who have the time required to receive training, build community consensus, and to develop strategies and detailed action plans.

It became clear that without a perceived community crisis, nothing would have happened. It was equally clear that coalition progress would be slow if leaders continued working only with primary stakeholders—busy people who are already involved in community efforts, which take much

of their time. To actually get any work done, leadership, community champions, and interested community members who had the time to engage in building community consensus were needed to accomplish the project's goals. The message to stakeholders was, "Send us 10 to 12 of your people to be engaged in the coalition. Let them receive training and develop strategies and action plans." And this process has to be replicated in every community.

North Carolina presents a good paradigm for understanding the challenges of introducing the comprehensive Project Lazarus model. Each of the state's 100 counties has diverse built-in prejudices and biases due to the stigmas associated with substance use and different belief systems. With education and patience, these beliefs can change over time. For example, as a result of Project Lazarus' testimony before the NC Medical Board in 2007, the Board promulgated in a best-practices recommendation that naloxone should be co-prescribed with an opioid analgesic to patients considered

LESSON LEARNED: Every community in North Carolina is different, ranging from sprawling urban cities to tight-knit rural towns in the mountains and along the coast, from US military bases to American Indian reservations. Each comes with its own built-in prejudices, biases, and belief systems. And as every community is ultimately responsible for its own health, its response to the epidemic of overdose deaths from prescribed pain medication, and to the increasing prevalence of substance use disorders among the citizens, will be equally unique.

to be at increased risk of opioid-induced respiratory depression, or to family members or peers who might observe a potentially fatal overdose. However, implementing this recommendation in routine pain management clinical practice continues to be a work in progress.

The Community-based ("Bottom-up") Components of the Project Model: Coalition Action

Anne Thomas, CCNC's Eastern Regional Consultant and retired Dare County Health Department Health Director, describes the Coalition Action element in the hub of the Project Lazarus Model. This element most closely corresponds to the second of the hub's four activities: the development of effective community-based coalitions to implement approaches to drug overdose prevention that will meet the community's needs.

Eastern NC is a primarily rural, diverse, and underserved area that covers a large geographic region, has a small population base, high poverty levels with limited economic opportunity, and pervasive and persistent

LESSON LEARNED: The portal of entry for forming community-based overdose prevention coalitions is different in each community, and finding one entity to establish the infrastructure statewide has not worked.

health disparities. Each community is different and has its own unique resources, infrastructure, politics, and will. One of the obvious points of entry to forming a community-based coalition is the local health department. Eighty five county health departments serve all 100 NC counties that have local autonomy in the state’s decentralized public health system. NC health departments are required to perform a comprehensive Community Health Assessment (CHA) every 3-4 years to identify health priorities, and to engage community partners and members to develop action plans to address these identified health issues, positioning them to learn if a substance abuse coalition exists in their community. If one does not exist, the health department may be willing to convene and facilitate such a coalition. Most health departments are skilled and recognized for their ability to bring the community together to collaboratively find solutions for their health problems in much the same way as Project Lazarus coalitions do. The CHA also catalogs assets and resources in the community, so health departments are the logical place to learn what the substance abuse resources are and where any gaps may be found. If local health departments are not ultimately selected as the lead for the community-based overdose prevention coalition, they are frequently a key stakeholder.

Finding an existing coalition that has a good track record, credibility, and wide stakeholder engagement that can expand the mission and membership is key in counties where health departments are unable or unwilling to establish one. While existing substance abuse coalitions constitute a logical starting point, they often already have a focused mission (e.g., addressing the issue of underage drinking or targeting certain at-risk groups such

as youth). As such, they may be seen as *a service agency* in the community rather than *a community change agent*.

To successfully implement Project Lazarus, substance abuse community coalitions need to be willing to expand their mission and membership to have a positive impact on the entire

LESSON LEARNED: A community-based overdose prevention coalition is not intended to be just another service agency; nor should it be convened to support the work of an extant agency. Instead, it should serve *as a catalyst and advocacy group for policy and social change* by targeting beliefs and perceptions, raising community awareness, and changing rules, regulations, policies, and practices in the community.

community, and to be a catalyst for community and social change. Helping them embrace and develop skills to effectively meet this expanded and potentially unfamiliar role as catalysts and advocates for policy, environmental, and systems change is important.

Once a coalition agrees to engage in this role, securing the buy-in and commitment of key decision makers to support the ongoing work of the coalition is imperative. The order and timing in which the larger community is mobilized, engaged, and empowered is crucial. Key stakeholder meetings must be held and followed 30 to 45 days later by a community forum where more people are invited to the table. This helps build awareness and interest across a wider community group and sets the stage for strategic planning and capacity building of the coalition. Engaging and sustaining key sectors over time requires an understanding of the collective mission and how the work supports each organization's individual mission. All stakeholders must understand why they are needed and what they can contribute. Establishing a mission and goals for the new coalition that are not specific to any existing organization or individual is recommended. Also, creating a name for the coalition, separate from any one organization, increases a sense of commitment, buy-in, and ownership.

LESSON LEARNED: Rural communities typically have fewer resources, training opportunities, and support systems to start and sustain a community-based overdose prevention coalition. They have a greater need for training around policy, environmental, and system change as they are often more comfortable with developing programs and services targeted at the individual, as opposed to the community.

Rural communities often have significant health challenges and limited capacity to address them. Finding strong leadership and people with passion and knowledge of the issue, and the ability to manage and coordinate efforts is important, as is the awareness of informal community networks and how they function.

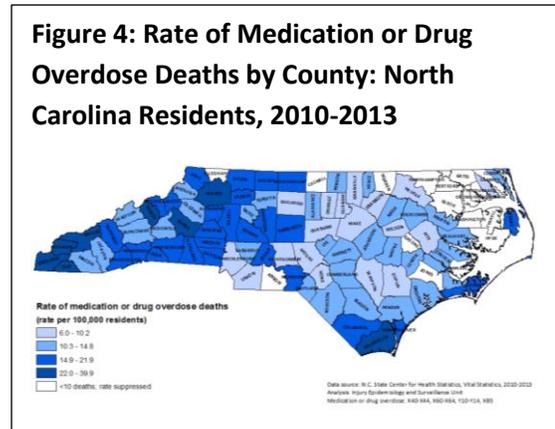
Identifying and engaging community

members who have been significantly impacted by prescription pain medication misuse, such as addiction or overdose, can be a powerful motivator and provide purpose to their life's journey. However, there must be support for these persons throughout the process. For instance, in Dare County, a woman who lost her son to a drug overdose helped serve as a change agent in the community for increasing resources for prevention initiatives and the treatment of substance use disorders. While telling her story was incredibly compelling and powerful, it was also, at times, very difficult for her.

The Community-based (“Bottom-up”) Components of the Project Model: Sustaining Coalition Action

Jenni Irwin, Director of the Coalition for a Safe and Drug Free Cherokee County, and an ongoing partner with Project Lazarus described sustaining the Coalition Action element in the hub of the Project Lazarus Model.

Like the counties in the eastern coastal plain of NC, most counties in the western third of the state are primarily rural, culturally and ethnically diverse, and economically challenged. As seen in Figure 4, the mortality rate from overdoses of prescribed pain medication is higher among the counties in the Appalachians than in the rest of the state, excluding a couple of counties directly on the coast. With funds received from Project Lazarus, Cherokee County observed a 93 percent decrease in deaths from unintentional prescription poisonings in 2012.



LESSON LEARNED: Identifying and engaging members of the community who have shown leadership skills in areas other than overdose prevention is critical in selecting those who can lead, promote, and sustain the coalition’s efforts.

Despite gradual successes, building and sustaining a community-based overdose prevention coalition in Cherokee County has been challenging. Purposeful recruitment from within the community to

participate in an overdose prevention coalition may be different from the recruitment of those who have the experience to take on leadership roles. Not everyone recruited for membership will have the talent or inclination to take on a leadership role, but their presence, participation, and influence will naturally encourage others to get involved and become invested in prevention efforts. This does not mean that a person duly qualified to promote an area of interest will necessarily remain in a leadership

LESSON LEARNED: It may be more productive and sustaining for leadership roles on an overdose prevention coalition to change periodically and last for shorter amounts of time, such as for one project goal at a time and not for the duration of the coalition.

position for the duration. For example, the Coalition for a Safe and Drug Free Cherokee County purposely recruited the Director of Emergency Medical Services (EMS) to assist the coalition in training EMS and law enforcement officers to carry

naloxone. The EMS Director met with the Fire Chief and assigned a liaison from the Cherokee County Fire Department to also work with EMS and the coalition leaders to develop policy and training for the county EMS and fire department employees. The EMS Director's leadership on the coalition in promoting naloxone training was instrumental in initiating this harm reduction policy and implementation process. Once the primary interest was achieved, he relinquished his leadership role and simply served as a coalition member.

LESSON LEARNED: Coalitions that embrace the role of change agent, in contrast to that of a service agency, can often sustain their effectiveness in periods of diminished funding by availing themselves of educational materials and technical expertise provided by Project Lazarus, and by institutionalizing overdose prevention strategies in other local organizations and agencies with similar missions related to preventing overdoses from prescription medication and other drugs.

Another strategy for maintaining leadership is through personal and public acknowledgement. Based on Jenni Irwin's experience in Cherokee County, this can be done easily and at no cost. The strategy of public recognition may seem frivolous, but individuals who are publicly acknowledged for their contributions have been more willing to take on other projects where they have been hesitant in the past.

The Cherokee County's overdose prevention coalition has survived several episodes of lean funding, often by making their goals and areas of expertise known to other organizations within the community that might have similar or tangential goals. For example, the coalition partnered with the Sheriff's Office when they were writing a prescription drug prevention grant funded through the NC Governor's Crime Commission. The coalition agreed to assist the Sheriff's Office in the media and community engagement components and it was written into the grant. Because the coalition and Sheriff's Office's goals met the same criteria, the coalition could allocate money it would have needed for communication to its other activities. Likewise, the health department included the coalition in a small grant proposal for prescription drug awareness in the amount of \$2,500 for media. This, again, freed up money the coalition had already allocated for media activities to be used in other areas.

LESSON LEARNED: Coalitions can gain stability and make progress when goals and strategic plans are clearly established, even during times of sparse funding, by co-opting funding for similar or shared missions and plans of other local organizations.

The Coalition for a Drug Free Cherokee County took advantage of other partnering strategies to sustain activities when it lacked any direct funding. As the coalition began working towards decreasing overdoses from

prescription pain medication, it saw the benefit in updating the local ED's prescribing policy using Project Lazarus' toolkits. These toolkits are designed to assist medical professionals in updating their prescription drug policies by giving examples of prescribing practices that have been successful in other EDs. The coalition first developed a partnership with the CEO of the local hospital to assist efforts to bring other medical professionals to the table. Project Lazarus made changes to the practice of medical care feasible by providing free educational training, which included the use of local prescription pain medication overdose data. Soon after this training, the ED adopted a prescription pain management policy regarding the administration of, and prescriptions for, narcotics and sedatives. The hospital CEO continues to promote the use of the toolkits to other medical professionals to establish the same type of policy.

Other examples of sustaining coalition activities in Cherokee County include developing partnerships with law enforcement officers and establishing 24/7 medication drop boxes, which continue to serve the community as funding opportunities diminish. The coalition also partnered with schools to develop data gathering tools for school improvement plans. The school has agreed to include the data tool in its budget, which is another example of institutionalizing the coalition's efforts. The coalition is currently working with the schools to develop and implement a policy which will include training bus drivers and school personnel on how to identify the signs of an overdose and to properly administer naloxone. School administrators have agreed to have naloxone available on school buses and in each middle and high school.

The Community-based ("Bottom-up") Components of the Project Model: Data and Evaluation

Nabarun Dasgupta, PhD, Co-founder of Project Lazarus, epidemiologist at IPRC, and Chief Science Officer and Co-Founder of Epidemico, describes one of the pieces of the Data & Evaluation element in the hub of the Project Lazarus Model. This element most closely corresponds to the third and fourth hub activities: the use of data to demonstrate the nature of these needs, and program evaluation to determine the extent to which the actions adopted and implemented are successful.

One of the core objectives of the Project Lazarus model is to determine if the interventions (identified in the spokes of the model) selected by each community-based coalition have led to changes in rates of outcomes, such as overdose or high levels of opioid prescribing. This evaluation should assess the rollout of Project Lazarus from one county in NC to all of its other 99 counties for not only its state funders (the Trust and the Office), but also for its federal funders (CDC). It needs to answer this key question: Can the Project Lazarus model be considered an evidence-based overdose prevention program for other states to adopt? Hence, the program evaluation benchmark for deploying Project

Lazarus in NC is a considerably higher bar than would be required for most prevention programs. Program evaluation can encompass a process evaluation (e.g., how well the rollout is progressing

LESSON LEARNED: All public health initiatives, especially new overdose prevention programs, benefit from outcome and process program evaluations. These evaluations will ideally draw on data from multiple sources. The type and degree of evaluation should reflect program needs and a clear appreciation of the limits of the data on which the evaluation is based.

programmatically, and what activities are being implemented, where, when, and to whom), and an outcome evaluation (e.g., Project Lazarus' effects on key public health indicators). The focus of this study is the latter, albeit drawing on selected data collected during process evaluation as well.

The first step in evaluating the statewide implementation of Project Lazarus was to look for existing data sources with statewide coverage. All states have vital statistics divisions that collect mortality data. Of all the outcomes, this is the greatest concern for many funders. One issue involving the use of mortality data, however is the potential lack of statistical power required to find an effect. The number of overdose deaths in NC is not sufficiently high at the county level to support highly specified modeling strategies, although descriptive statistics are feasible. Two issues should be considered when choosing a mortality data source. First, encoded vital statistics data from death certificates are constrained by coding protocols and lack complete medical histories. Second, medical examiner investigations are only conducted on a subset of all overdose deaths, and autopsy practices are often idiosyncratic across counties. However, these data are official numbers and can be compared with national figures to help benchmark the effectiveness of the intervention in the state.

LESSON LEARNED: Although reductions in overdose mortality is often considered the most important outcome by which funding agencies track program success, the number of deaths by county, over time, often lacks adequate statistical power to provide highly detailed feedback. Nevertheless, mortality data can be aggregated to the state level for a full year to be meaningful.

LESSON LEARNED: Hospital data are becoming readily available and can be used for overdose surveillance for outcome data; however, due to considerable variation across hospitals in coding overdose-related encounters and limited specificity in identifying opioids, findings should be interpreted with caution.

Hospital data (including hospital discharges and ED visits) are becoming more readily available as electronic medical records systems are required to show

public health applications for the data they collect, known as meaningful use. Many of these systems were originally established to provide early warning for infectious disease outbreaks and bioterrorism events. When repurposed for overdose surveillance, these data can provide a very rapid and clinically verified source of outcome data. Visits can be tracked down to the hour and minute of admission. However, there is considerable variation across hospitals in how they code overdose visits, so using these data require standardizing processes on the ground, or at least understanding and taking biases into account. Further, and as with mortality coding, ICD-9-CM has limited specificity as an indicator of which type of opioids are involved in the medical encounter. The biggest limitation to hospital data is that they cannot be used to directly calculate prevalence or incidence of outcomes because access to healthcare is not uniform, and motivations for seeking care are unrecorded.

Prescription monitoring programs, or PMPs, are statewide electronic databases used by providers at the point of care to look up patients' histories of dispensed

LESSON LEARNED: While data from PMPs are detailed and informative, the databases are enormous, require extensive cleaning and analysis, and are limited and do not provide information about what medical condition prompted the opioid prescription.

outpatient prescriptions for controlled substances. The data are generated when outpatient pharmacies upload records for each controlled substance dispensed. These data are inclusive and have detailed drug information. They can be used to derive, for example, the number of prescriptions, opioid patients, prescribers, the distance traveled for prescriptions, the method of payment, and the number of people receiving multiple drugs at once. The structure of these databases allows great flexibility in designing the most appropriate outcome for the study, beyond overly simplistic metrics such as the number of prescriptions received. However, the datasets themselves are enormous and need to be cleaned and analyzed using a server with very large capacity. The data also take considerable effort to format for analysis, but IPRC will share its code freely with all who request it. A further challenge in interpreting PMP data is that there is no way to know what medical condition called for an opioid prescription (e.g., cancer vs. non-cancer pain).

To account for other factors influencing the outcome, collecting information on potential confounders—that is, factors or conditions that may provide an alternate plausible explanation for what is found is essential. These should be collected at the same geographical and temporal resolution as outcome and exposure variables. A benefit of conducting community-level analyses is the ability to bring in information from other public data sources. For example, the Area Resource File produced by Health

Resources and Services Administration (HRSA) can be used to determine the number of hospital beds or doctors in a given locale, and Census variables can be integrated as well.

Collecting exposure (independent variable) data can be more challenging than collecting outcome (dependent variable) data. For example, how does one know how much of an intervention has been administered, where, when, and to whom? How does one know how completely the intervention was implemented—that is, with what level of fidelity—and over what period of time?

LESSON LEARNED: Process evaluation data are often collected for grant reporting, which may introduce over-reporting bias if the reporter seeks to reassure the funder that all promised activities were implemented as intended.

These are difficult questions that generally require creative data collection and explicit assumptions in how data are modeled. The more centralized the intervention, the easier

the data may be to collect. The groups responsible for interventions and trainings often have process logs that record the number of attendees or the amount of pills collected at a pill take-back event.

Online forms that collect survey data from targeted stakeholders have been routinely used to evaluate the rollout of Project Lazarus. For example, once a year, an invitation to fill out an online survey is sent to all local health directors to report on the climate and readiness for drug abuse prevention programming in their respective counties. This assessment allows for statistically accounting for the lack of randomization in the implementation of Project Lazarus (which reflected the demand of one funder while giving preference to early adopters). The data will be fed into the model as contextual information that will facilitate control for fundamental differences across communities, and for mathematically leveling the playing field for the counties by using propensity scores or similar methods. Survey data from coalition leaders are also collected to understand how well the coalition is functioning and communicating. The measures being used will help quantify the strength and effectiveness of each coalition.

LESSON LEARNED: Securing a full and timely response to surveys requires considerable follow-up and adds to costs and to study personnel time.

Linking all of these data together begins by defining the smallest unit of time and space for getting reliable information across all

sources. In this evaluation, the county-month, that is, each row of the analysis table corresponds to the various activities that were administered each month in each county. So, with 100 counties in the state, for 5 years there would be 100 counties x 5 years x 12 months per year = 6,000 rows. While some data

are available at a more granular level, like the hour of the day of any given ED visit, the month was the smallest unit of measure that could be asked for recall by coalitions. Each column variable corresponds to one of the measures above, giving nearly complete data for the whole state and for the whole study period. Poisson or Negative Binomial models were used to estimate rates, which provided a robust sample size.

Because the data are all in disparate time and geographic formats, a database called “the Matrix” was created. Aggregated data was collected at smaller time units, such as days, into monthly counts. For example, by having access to the line-level (or record-level data) in the PMP, the number of unique patients living in North Carolina receiving opioid analgesics each month could be calculated in each county. More advanced measures are available, such as the number of unique patients filling temporally overlapping benzodiazepine and opioid analgesics scripts, or the number of patients younger than 18 who are filling prescriptions for opioids.

The geographic unit selected was patients’ and providers’ county of residence. By focusing on NC residents, prevalence rate ratios could be calculated using resident population as the denominator, which is more straightforward to interpret than odds ratios. Most data sources identified the county of residence. While analyses were limited to NC residents, the whole dataset was examined with sensitivity analyses to see if interstate migration has an impact on findings.

The largest limitation to this methodology is inter-level or ecological bias. The Project Lazarus analytic models assume that what happens at the county-month level uniformly impacts every county resident. This is a common problem in surveillance-based evaluation studies, and the same assumption is made when comparing mortality rates for overdose between states. Therefore, the data will need to be interpreted carefully and these findings couched to acknowledge this assumption. In addition, where linking datasets by name is not possible, individual-level studies will be conducted with pairs of data sources to assess the impact of inter-level bias.

Perhaps the most challenging aspect of data collection for program evaluation has been requesting data use agreements and keeping track of all the unique requirements that each data provider imposes. If it is tricky with one source, having a dozen is that much worse. Data use agreements for some major data source are being renewed nearly

LESSON LEARNED: Keeping abreast of the methodological changes in each data source gives confidence to the agency responsible for collecting the data that it will be used responsibly. This may include paying attention to funding decisions by the state legislature and personnel changes within health departments.

every other month. This requires organization and maintaining strong relationships with data providers to ensure that data are not used or reported in a way that is not sanctioned by the agreement.

Staff turnover at all levels (in the Project Lazarus office, CCNC, UNC IPRC, the 14 CCNC networks, and the funding agencies) has been a challenge. Explaining the overall vision is difficult, let alone the details of each of the evaluation's multiple data collection efforts. The key question is, How do we justify

LESSON LEARNED: The more the study's methodology is presented, the clearer the message becomes. Plans for the study design must be run by wide types of audiences and stakeholders at different levels of scientific aptitude.

to the data owner or gatekeeper our need to have access to the data? Part of the solution is to have simple documents that lay out the vision and show how all the pieces fit together.

Dynamic meticulous recording of metadata is essential; a codebook will no longer suffice. After trying many different approaches, to keep track of the Matrix, a secure message board and file organization software that allows the creation of discussion threads for each data source was selected. This online space serves as a repository for everything from raw data, to programming code, to finished slides. Every change to the data is documented in chronological order, and the SAS and Stata code are posted here as well. By integrating into email, the software archives all conversations to document how decisions were made, independent of staff turnover and retiring email accounts.

LESSON LEARNED: Writing the methods section for a publication is much easier when the author does the data cleaning.

After posting the code and transformed datasets to the message board, three to five sentences of methods text are written for each that can later be cut and pasted into

manuscripts. These include basic sample size descriptions, data cleansing steps, and variable creation.

Finally, the research ethic of "nothing about us without us" is key. Including groups such as the North Carolina Harm Reduction Coalition (NCHRC) helps keep the research focused on topics that will actually help the lives of people who abuse drugs, and encourages the collection of feedback throughout the process.

Part 2: Implementing Project Lazarus in North Carolina: Lessons Learned from the Project Lazarus Model

The Intervention-based (“Top-down”) Components of the Project Model: Community Education and Pain Patient Support

Fred Wells Brason, II, chaplain and Project Lazarus CEO, describes the Community Education and Pain Patient Support element in the spokes of the Project Lazarus Model. This element most closely corresponds to the spoke activities that target medical providers and focuses on clinical guidelines.

LESSON LEARNED: Meeting a community’s needs and bringing about the desired change that addresses the epidemic caused by prescribed pain medications requires a balanced and comprehensive approach.

Whether the focus is on community or provider education, diversion control, or any of the other activities identified in the spokes of the Project Lazarus model, misuse and abuse of prescribed opioids, heroin, benzodiazepines, and other drugs

associated with unintentional poisonings must be prevented. Similarly, appropriate and accessible patient care must be ensured for people adversely affected by these potentially dangerous drugs. Specifically, to meet the needs of those who misuse opioids, providing responsible pain management should continue while also promoting substance use disorder and addiction treatment, as well as support services within communities. Every population, every age, in every community must be reached with appropriate messages that promote appropriate and safe practices related to medications. That is why addressing this epidemic from a public health, top-down, and bottom-up perspective is important—outreach promotes sustainable community consensus and support.

As described earlier, the hub and spokes of the Project Lazarus Model cover many different

LESSON LEARNED: Engaging the general public requires connecting the dots in their lives to show why they need to be engaged. Three basic questions need to be posed: 1) Why am I needed? 2) What do I need to know? 3) What needs to be done?

areas. Once there is a general awareness that people in the community are dying from prescribed pain medications and other drugs, community education is crucial. Community education must reach everyone, at every age, regarding their perceptions, misconceptions, and

behaviors related to the medications they keep in their homes.

When the Project Lazarus approach was first started in NC, much awareness building was needed about the misuse and abuse of prescription pain medication. Working with each specific

population group and community sector, allowed for framing messages to show why each needed to be involved, what each needed to know, and then what each could do. Each group and community was invited to become connected and to take action to bring about a change in behavior. These behaviors included ensuring that prescription medications are always locked up, taken correctly, stored securely, disposed of properly, and never shared with others.

Local data are required to drive the messaging and the reality of the situation within each community. Data can drive change in practice, policy, and guidelines, and foster a comprehensive community public

LESSON LEARNED: Statistics often need to be translated and their relevance should be communicated for the general public within every segment of a community.

health approach. Obtaining and interpreting national, state, and local data is also important for making the situation understandable to the community. For example, when data concerning prescription practices were provided to local communities that found they were above the state average, they quickly recognized the need to change the prescription practices of their medical care providers. However, arbitrary decreases were demanded within the community—anywhere from 10 to 40 percent. There was little recognition of a basic principle of statistics: by definition, some communities will have prescribing rates either above or below the state average. There was no surprised that the prescribing rates of pain medications in Wilkes County, for example, were (and continue to be) higher than the state

LESSON LEARNED: No one optimal rate for overdose mortality or opioid prescribing exists. Every community is different.

average, even though those rates have decreased over the past 5 years. The goal has been to ensure appropriate prescribing that puts safety and education mechanisms in

place so that every patient is adequately served and protected.

Changing community norms is complex. Reaching the community involves working with both individuals and the environmental context in which they live. Each individual and family has biological, psychosocial, social, and spiritual factors that need to be addressed, as illustrated in Figure 5.



Figure 5: The Impacts of Environmental Factors on the Individual

Project Lazarus sought to impart knowledge, education, and understanding to communities, helping them

LESSON LEARNED: The biggest obstacle to reaching those who need help and care by changing community norms is counteracting the myths that result in stigmas and prejudices.

select and implement a strategy that represents a “best practice” in the prevention field. The lack of knowledge and understanding hinders wise decision making, impeding progress. Many communities have often viewed any kind of drug-related issue as a personal situation that results from some moral failure or as an individual behavioral issue and thus, not as a public health concern. Showing that safely prescribing pain medicine and overdose prevention are broad-based public health concerns, and that remedies can be fashioned in response is important. The challenge is that many communities lack the organizational structure or the will or desire to identify and collaborate with the multiple players necessary to address the complexities of this drug epidemic. In part, that is due to the different levels of resources in various organizations within the community.

LESSON LEARNED: The availability of entrenched leadership willing to promote Project Lazarus, rather than the rate of overdose mortality within the community, was the most effective predictor of implementation success and sustainability.

From a data perspective, it was originally assumed that Project Lazarus should be rolled out in the most affected communities. However, realizing that was not necessarily the case came early. The project intervened

in communities with energy and political will. For example, effort was focused on communities where an individual, group, or organization was already active in or made known the desire to do overdose prevention work. Investing in the leaders of community-based work was shown to yield quicker program implementation and greater sustainability. The best approach was to come in as an outside source for support, with money, materials, and education. The community then, needed to move forward on their own terms. Enabling community-based stakeholders to work independently and not to rely on the project and other outsiders would result in sustainability and bring about long-term change.

An important lesson from Project Lazarus is the need to explicitly promote pain patient support as one of the seven specified intervention categories is critical. Setting up mechanisms to support people living with pain is just as essential as all of the other spokes in the model. While the misuse and abuse of prescription pain medication should be addressed, it is equally significant that it is accessible, appropriate, and safe for patients. Strategies are needed to ensure that these patients' pain is reduced to a level that allows them to maintain the life they desire to live. Thus, the Project Lazarus model stresses meeting people who live with chronic pain where they are and helping them get to where they want to be.

LESSON LEARNED: A support network for those with chronic pain is sorely lacking within almost every community.

Looking into the entirety of a person, including their culture and environment, and their physical and spiritual wellbeing, is both important

and necessary. Pain patient support requires providing therapies other than medication that can help abate pain. Alternative approaches include physical therapy, music, breathing, wellness, nutrition and exercise, prayer, meditation, yoga, and acupuncture. In short, many alternatives to pain medication exist, but unfortunately they may be neither available nor familiar, especially in rural communities.

One way that Project Lazarus has implemented pain support is by collaborating with CCNC, NC’s Medicaid infrastructure. A successful strategy has

LESSON LEARNED: Integrating behavioral health into the general primary care services compensates for lack of resources and referral mechanisms available in most communities.

been working with the CCNC care managers in the Chronic Pain Initiative. These mid-level professionals complement medical care provider treatment by addressing the biopsychosocial aspects of every patient they serve. Implementing pain patient support services is as varied as the regions within the state. However, Medicaid practitioners are generally prescribing opioids appropriately and safely when treating pain, and by having behavioral health services available “in house,” they can treat the whole patient so that their full biopsychosocial characteristics are addressed.

Home health services is key to pain patient support. These services act/function as the practitioners’ eyes and ears in the home. Although they cannot be engaged with every pain patient, however where available, home health can provide home education, promote overdose awareness, and reinforce the importance of taking medicine as prescribed, storing it securely, disposing of it properly, and never sharing it.

LESSON LEARNED: It takes a local spokesperson who has lived with chronic pain, working in a peer-to-peer approach, to get the right people talking to each other.

Another component to pain patient support that differentiates Project Lazarus from other overdose prevention programs is the role of the pain patient as a community advocate.

People like Diana, a Wilkes County Project Lazarus spokesperson, who has lived with chronic pain for decades—in other words, “walked the walk”—knows about the circumstances that characterize those who live with pain, and who have built an integrated medical and personal support system. Community advocates can make a difference and can lead people into better care, initiate better practices, and help the entire community.

The Intervention-based (“Top-down”) Components of the Project Model: Provider Education and Hospital Emergency Department Policies

LESSON LEARNED: Previous experience is clear that to be effective, behavior change, including prescribing opioids, is extraordinarily difficult and requires technical assistance including mentoring, skills development, and most of all, systems redesign.

Dr. Sara McEwen, Executive Director, the Governor’s Institute on Substance Abuse, describes the medical care provider education and opioid prescribing policies spokes of the Project Lazarus Model.

The Governor’s Institute (GI) is a nonprofit organization that has been providing training and workforce development for physicians and other health care providers for more than 20 years. Prior to the rollout of Project Lazarus across NC, the GI implemented the Safer Opioid Prescribing Project for the Trust. Because of its existing strong relationship with CCNC, primary care and behavioral health communities, professional boards, and state and federal agencies, the GI assumed responsibility for the clinical training component of Project Lazarus. Forty 3 hour core trainings were held across the state between 2012 and 2014: 20 Category 1 Continuing Medical Education (CME) trainings through the NC Academy of Family Physicians, and 20 non-CME trainings (with the support of Pfizer). The CME and non-CME trainings were essentially identical. Prescribers and pharmacists constituted the primary target audience, but other partners’ attendance was wanted as well so links between primary care and local specialists in behavior health and pain management could be established or strengthened. Applying skills and tools to aid implementation was the focus.

Two presenters were used for each training, which made it more interactive and modeled the type of collaboration between primary care provider and pain specialist that was wanted. The trainings drew from a pool of eight core trainers from different medical specialties, all of whom had addiction medicine expertise.

LESSON LEARNED: The cognitive buy-in to the principles of Project Lazarus was not all that difficult. The challenge was getting the right people to the table and implementing the required practice changes.

When possible, a local person (e.g., a public health director, CPI coordinator) presented some statistics and epidemiology specific to each location to make it clear to the audience why this was

LESSON LEARNED: Many practitioners are unaware of the availability of behavioral health and substance use disorder resources in their own communities. Accessing and using these resources needed to be reinforced as part of the case studies, discussions, and didactic material presented during each training.

significant for their community. It was important to introduce each session by saying that Project Lazarus was there to help with their identified problem, and could provide information and tools to help them work more effectively with some very complicated and challenging patients. Local behavioral health resources were identified and intentionally invited to the training sessions. Each training also included regional pain management expertise. Singling out local consultation and referral options was an important part of the model. Not only were the pain physicians a vital part of the trainings, but they were also part of ongoing technical assistance provided after the training. The Pain Society of the Carolinas was used as outside technical experts to help recruit and screen the potential pain specialists who could serve as local mentors. An explicit goal of the training sessions was to facilitate enduring local partnerships with pain and substance use disorder experts. This has worked well in some places, and less well in others. Overall, most experts have been underused.

The evening training sessions consisted of an overview of chronic pain, using Pfizer’s Pain Narrative, assessment and risk stratification, framing opioids as a time-limited trial,

LESSON LEARNED: Educational content about safely and appropriately prescribing opioid analgesics should be framed so practitioners are not unintentionally deterred from prescribing any opioid-based medications.

and monitoring and intervening with aberrant behavior. It was crucial to communicate the need for careful screening, monitoring, and vigilance without “scaring off” practitioners who might decide not to prescribe at all, as has happened in some states. Addressing stigma and preconceived notions about so-called “doctor shoppers” was also essential. Considerable time was thus devoted to differentiating addiction and physical dependence and chemical coping. Concepts were illustrated and practiced

LESSON LEARNED: The curriculum needs to be continually modified to reflect evolving best practices, in spite of the general appeal of continuity and consistency of its use over even a relatively short (2 year) period.

throughout the trainings via ongoing case discussions among the core presenter, pain specialist, and audience.

Trainings were standardized because the statewide rollout of Project Lazarus is a CCNC initiative and its funders placed great importance on combining multiple chronic pain educational programs in the country into a single, comprehensive initiative. However, updates were made along the way to accommodate the rapidly evolving nature of overdose prevention in the state and the country, largely by including ancillary materials. Some of the major tools and ancillary materials included the Federation of State Medical Boards' and the North Carolina Medical Board's updated position statements on the treatment of chronic pain, especially with opioid analgesics, upgrades and guidance on registration and use of the state's prescription drug monitoring program, and the rapidly changing landscape concerning the co-prescribing and community-based distribution of naloxone. Updates also included the state's 911 Good Samaritan law, CCNC's Pregnancy Medical Home's development of Care Pathway and guidelines for opioids in pregnancy, and the GI's development of video training modules concerning urine drug screenings and using the state's PMP.

The collaboration between GI and Pfizer was a novel approach to designing and implementing the medical care provider education component of the Project Lazarus model. Pfizer was one of stakeholders on the advisory group and provided support for 20 trainings, which allowed for 40 trainings in all. Pfizer was also responsible for *Pain Narrative for Primary Care*, which served as basis for the first part of the core training. Although the collaboration was productive, there were challenges. Pfizer's trainings had to be for non-CME credit, so there was less demand and they were not as well attended. Working through Pfizer also limited the speaker's bureau. Pfizer was undergoing a corporate reorganization, which meant that the detail representatives assisting with recruiting medical care providers to the training sessions were new to their areas and often did not have contacts.

LESSON LEARNED: Changing the clinical practice culture of pain management in emergency departments was more difficult than anticipated. The “bottom-up” advocacy of the leadership of community overdose prevention coalitions had more impact than the “top-down” educational training offered.

One of the more challenging aspects of recruiting medical care practitioners to the educational training sessions was getting providers who work in EDs to attend. Attempts to train ED

doctors separately were only minimally successful. The problems often revolved around time, shift work, and culture. Furthermore, many practitioners who work in EDs are employed by multiple hospitals that have different ED policies for treating patients with chronic pain, opioid prescribing protocols, and access to the PMP. There was also the issue of “Press Ganey” patient satisfaction scores that can have a bearing on hospital and physician compensation and can reduce providers' willingness to deny their pain

patients opioid analgesics. EDs and CCNC had more of a disconnect than anticipated. Closer ties were expected between Medicaid networks and EDs as well. The best ED engagement strategy seemed to be related to distributing naloxone to law enforcement officers who often assist at overdose events.

LESSON LEARNED: EDs are neither appropriate nor equipped for relatively complicated pain and behavioral health assessments or treatment.

Successes were achieved, in part because Project Lazarus and CCNC leadership and community coalition campaigns were a collective force in promoting the modifications to the state's PMP that were particularly

helpful to EDs and ED doctors. Project Lazarus and CCNC advocacy were likewise instrumental in convincing several major hospital systems to adopt new system-wide opioid prescribing and patient referral policies for their EDs. Though hospital CEOs, COOs, and other administrators were invited to attend the trainings, they were intentionally very prescriber- and pharmacist-focused. Diluting their content might result in losing the primary audience.

Hospitals were initially uncomfortable about implementing restrictive prescribing policies, and then about having poor patient satisfaction Press Ganey scores. Although this was initially seen as a potential barrier, it was less pivotal than anticipated. The take-home message is that hospitals need to be willing to accept initially poor scores that, at least in this NC experience, right themselves after a specific hospital ED establishes a restrictive opioid prescribing policy that becomes known to prospective patients.

Current work includes an online training that comprises a three module, 3 hour CME session with videos and Q&As. The hope is that the major malpractice carriers will award "risk reduction" points for physicians who complete the training, a practice that has been implemented successfully in Colorado.

The Intervention-based ("Top-down") Components of the Project Model: Harm Reduction

Tessie Castillo, Communications and Advocacy Coordinator, the NC Harm Reduction Coalition, describes the harm reduction spoke of the Project Lazarus Model.

The harm reduction spoke of the Project Lazarus model is an excellent way to illustrate lessons learned when multi-partner collaborations deal with a challenging component of overdose prevention. The NC Harm Reduction Coalition (NCHRC) is a statewide nonprofit dedicated to reducing the negative consequences of drug use, including many components of traditional drug overdose prevention programs. They aggressively promote the use of naloxone, the opioid overdose antidote, to everyone who is at risk of suffering an overdose. NCHRC and Project Lazarus have the same goals of reducing

opiate overdose in the state, although the coalition often works with very different populations. Project Lazarus works through a naloxone co-prescribing medical model. NCHRC distributes naloxone directly to people at risk for overdose on the street level, including those who are actively using non-medically prescribed opioids.

Some of the populations to whom naloxone is distributed in the state are uniquely served by the NCHRC, such as those who use heroin and have no interaction with the medical care community. In contrast, the population that is prescribed opioid analgesics for pain management from medical care providers, and neither seek nor use opioids from any other source, are the primary target population for Project Lazarus and are rarely approached by NCHRC.

LESSON LEARNED: Two crossover populations have harm reduction and medical model overdose prevention programs in common: people who use pharmaceutically manufactured opioids obtained from both licit and illicit sources, and people who are potential witnesses to an opioid overdose who could be trained to recognize and reverse it using rescue breathing and naloxone.

Over time, it has become clear that another equally important opportunity for collaboration existed between the NCHRC and Project Lazarus: identifying and training the community-based distributors and users of naloxone within mutual and separate spheres of interest. The broader overlap in this area can have synergistic results. Whereas Project Lazarus works primarily with medical providers who treat patients with chronic pain, NCHRC work with community-based physicians who can provide the standing orders required for volunteers to distribute naloxone, particularly within the drug using community who rarely go to medical care providers. Both NCHRC and Project Lazarus have worked separately and jointly to successfully convince law enforcement agencies and first responders (such as firefighters and EMTs) of the validity and applicability of the principles of harm reduction. Potentially

LESSON LEARNED: Few significant changes in most aspects of overdose prevention begin without legislative sanctions. There is never a bad time to seek the passage of enabling legislation, regardless of the political persuasion of the legislature.

fatal overdoses require an appropriate response: they should be treated as medical emergencies with a focus on saving the person's life first—the opportunity for diversion control is second.

The NCHRC worked with a broad coalition of advocates, including many from Project Lazarus, to pass a 911 Good Samaritan law in 2013. This law provides limited immunity from some drug offenses to people calling 911, thereby encouraging them to call authorities without fear of prosecution. It also

provides civil and criminal liability protections for medical providers who prescribe naloxone and for bystanders from whom it is administered. Naloxone distribution is allowed through a provider's standing orders, whereby a prescription is issued to people who meet certain characteristics (e.g., at risk for opiate overdose), as opposed to a single patient.

While medical care providers are warming up to the idea of co-prescribing naloxone for patients to whom they prescribe opioids for pain management or treat for substance use disorders, NCHRC was clear that something needed to be done to address the immediate problem of people dying, so they started distributing naloxone directly to anyone at risk for an opiate overdose and their loved ones.

Figure 6 illustrates that between August 2013 and June 2015, the NCHRC has distributed more than

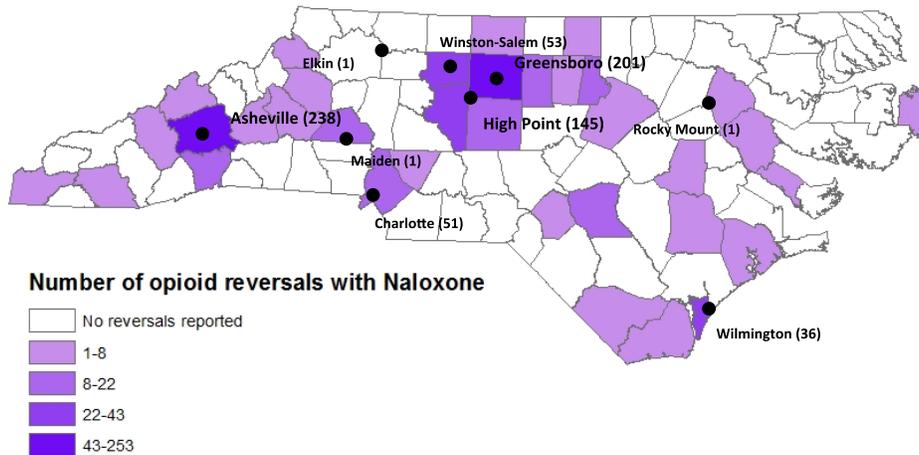
LESSON LEARNED: Practitioners should not assume that a new naloxone provider or user will only be willing to use one type of delivery system. All options should be discussed.

11,000 naloxone kits, resulting in 588 reported reversals to date by lay people with no medical background other than the training provided by the NCHRC. The NCHRC and Project

Lazarus collaboration has resulted in an expanded program of opioid education and naloxone distribution throughout NC. For example, the NCHRC can distribute Evzio auto-injectors^(TM), NCHRC intramuscular syringes, and naloxone vials, and can facilitate the distribution of Project Lazarus naloxone reversal kits to police agencies, first responders, outpatient substance use disorder treatment centers, and pain management programs across the state.

Number of Opioid Overdose Reversals with Naloxone Reported to the North Carolina Harm Reduction Coalition by County

8/1/2013 - 10/1/2015



5 reversals in an unknown location in North Carolina and 12 reversals in other states reported to NCHRC.



Source: North Carolina Harm Reduction Coalition, Oct. 2015
Analysis: Injury Epidemiology and Surveillance Unit

North Carolina
Injury & Violence
PREVENTION Branch

Figure 6: Number of Opioid Overdose Reversals with Naloxone by County

LESSON LEARNED: Users are less likely to call a phone number or visit a Web address to report reversals even if they are prominently listed on the kit.

As of now, there is no centralized mechanism to document the distribution of

naloxone or to record the number of overdose reversals based on the naloxone dispensed by NCHRC or Project Lazarus in NC. Informal reports to NCHRC volunteers appears to be the only viable, albeit recognizably incomplete mode of tracking. Despite the limitations inherent in the NCHRC data collection strategy, the number of overdose reversals just using NCHRC kits is impressive. Unfortunately, the reversals reported at each site are more a reflection of the efficacy of local data reporting methods than of an indication of where most overdoses are occurring, or even how many kits have been disseminated. The largest reporting sites are the several local methadone clinics where kits are distributed regularly. Distribution at methadone clinics allows an outreach worker to return to the same site every 3 months

to ask patients who have already received a kit if they have used it. People are much more likely to report use in person to an outreach worker on site than to contact that worker after the fact via email, phone, or in person.

LESSON LEARNED: Within North Carolina and across the country, documenting the distribution of naloxone, the number of reversals, and the collaborative work that fosters the community-based distribution of naloxone continues to be challenging.

NCHRC actively consults with organizations that represent potential partners who, when trained, can help reduce the number of people who die from an opioid overdose. During the last several years, NCHRC has seen the need to more actively involve law enforcement in overdose prevention and to help change the perception of law enforcement officers. They are not just the men and women who arrest the drug dealers to reduce the source of drugs, but they are often the first on the scene when a person's life hangs in the balance. According to an NCHRC survey of law enforcement, 90 percent support carrying naloxone. To actively recruit and train this unlikely, and until recently, untapped cadre of overdose witnesses, NCHRC, in a joint effort with Project Lazarus, has trained 14 law enforcement departments. NCHRC's work in NC shows the need to focus on the three best practices for distributing naloxone across the state:

LESSON LEARNED: Making the oft-held assumption that law enforcement is an unwilling partner in our work can be dangerous.

- 1. Standing Orders** – Before the passage of legislation allowing naloxone to be distributed through a provider's standing orders, patients had to visit a doctor to be prescribed naloxone. Numerous barriers stood in the way, including lack of insurance, reluctance to admit drug use to a physician, or the physician's reluctance to prescribe naloxone. Standing orders allow naloxone to be distributed to a group of people who meet certain criteria (e.g., those at risk for overdose).
- 2. Mobility** – In recent years, NC has seen the emergence of different types of naloxone distribution programs, including those that distribute from a fixed location and those that distribute via outreach workers who go out into the community. The mobile programs are overwhelmingly more successful considering number of kits distributed.
- 3. Distribute Through Peer Networks** – The best way to reach drug users, who are often mistrustful of authority, the medical system, etc., is through trusted peers. NCHRC's most

successful naloxone education and distribution sites distribute almost exclusively from user to user. Users can make the connections with people at high risk instead of waiting for a traditionally attention-shy community to come to them.

During the last several years, NCHRC has successfully implemented numerous strategies to counter some of the challenges encountered:

1. **Funding Naloxone** – There is never enough money to buy naloxone. Use the cheapest route possible (intramuscular with stripped down kits), such as seeking small city grants, and taking advantage of free or reduced price programs from pharmaceutical companies.
2. **Overcoming Myths about Naloxone** – Education will always be needed to counter the myths inherent in the principles of harm reduction. Overcoming the myths that naloxone encourages drug use or sends the wrong message has been difficult. Law enforcement and some medical providers were initially resistant about the program’s distribution of intramuscular naloxone. These barriers were overcome by education and demonstration of need. There is now abundant literature that shows naloxone does not promote drug use. Regarding syringes, the ones distributed are not the same syringes used to inject drugs and also, given the absolute necessity of naloxone distribution to save lives, IM naloxone is the most cost effective alternative available.
3. **Reaching across the State** – Naloxone is distributed through a peer network of active volunteers. NCHRC has only three staff members, but more than 100 distributors across the state.

The Intervention-based (“Top-down”) Components of the Project Model: Diversion Control

Donnie Varnell, Special Agent-in-Charge, NC State Bureau of Investigation (SBI), Diversion and Environmental Crimes Unit, describes the diversion control spoke of the Project Lazarus Model.

The Diversion and Environmental Crimes Unit investigates drug diversion by licensed healthcare professionals and others involved in the healthcare registrant field, large scale or multi-jurisdictional prescription fraud cases, suspicious deaths in healthcare facilities, and overdose related homicides. The unit provides training in diversion investigations, prescription drug abuse awareness, and environmental crimes investigations, such as violations of state and federal statutes and regulations including the Clean Water Act, or other violations involving pollution or hazardous substances.

LESSON LEARNED: Partnering with local agencies, such as Project Lazarus, Community Care of North Carolina, and the Injury Branch of the Division of Public Health that have similar goals, can compensate for inadequate staffing and has extended the diversion unit’s capacity to reduce the impact of illicit controlled substances within the state.

Several initiatives, including medicine take back programs, the funding and placement of “drop boxes,” and the prevention of opioid overdoses through the distribution of naloxone have

been collaborative and supportive efforts.

To help combat the abuse and diversion of prescription drugs in the state, the unit implemented a training program on the role of diverted prescription pain medicine in law enforcement for local, state, and federal officers. Over time, the program has been tailored to reach other communities such as medical professionals and local youth. While reducing access to illegitimate prescription drugs was an obvious step, unit data show that most drugs are obtained for free, from friends or relatives, or from a doctor. Providing information

to unit officers was an important part of continuing education to the community at large in community forums on

LESSON LEARNED: Building community awareness of the dangers of the misuse and abuse of prescription pain medication can gain additional credence and community buy-in when presented by law enforcement.

what behaviors increased a person’s chance of overdosing, and in turn what steps should be taken during a possible overdose. These teaching points have been well received by both law enforcement and the public.

After the early success of Project Lazarus and the work of the Harm Reduction Coalition, the SBI needed to be in the forefront of the state’s law enforcement participating in the naloxone program. Some obstacles were involved during the process. The two most pronounced included the liability of providing medical treatment without being requested, and the cost of acquiring naloxone kits.

With the help of Project Lazarus and the NC Harm Reduction Coalition, the SBI Bureau management team were informed about policies being used by other law enforcement agencies across the country. These policies were then tailored to fit particular needs.

LESSON LEARNED: Using the positive experiences of law enforcement from other states in community-based distribution of naloxone was a critical component in convincing the local administration to allow unit officers to carry naloxone.

As for the cost of the program, the unit had the initial kits donated. Management decided that follow-up

or replacement kits can be appropriated through general funds or drug seizure assets. Positive press that came from “saves” enacted by other departments was used to promote the program to management.

LESSON LEARNED: The DEA would have stopped sponsoring Pill Take-Back Days as of fall 2015 were it not for intense national community advocacy for continued support.

The Naloxone Program would be a lifesaving tool for various people. Not

only would it save the chronic drug abuser, but having unit SBI agents carry naloxone means that other lives can be saved, such as those of the elderly who take the wrong medication, or young people who accidentally ingest these medications. This policy has caused several other large state and local departments to inquire with SBI about what steps should be taken to carry the kits.

Much of the epidemic of opioid analgesic misuse is the result of generous people misguidedly (and illegally) sharing their medication with others, or leaving them around to be stolen. Diversion control of prescribed pain medication frequently begins in the home, which often serves as the repository of expired and unused opioids. One diversion prevention strategy has been to reduce access to these drugs by facilitating patients’ and family members’ clean out of medicine cabinets. Operation Medicine Drop (OMD), a diversion control program housed in the NC Department of Insurance, is a partnership of Safe Kids North Carolina, SBI, Community Anti-Drug Coalitions of NC, Project Lazarus, and local law enforcement agencies. All are working together to encourage the public to safely dispose of unused, unwanted, or expired medication. Since 2010, OMD has collected nearly 70 million dosage units of medication at more than 1,600 events held in most of the state’s 100 counties. In NC, pills are collected during biannual pill take-back days and from pill drop-boxes that are housed in local law enforcement offices for use by the community on an as-needed basis.

Pill take-back days and drop-boxes are successful strategies for removing excess drugs from the community that can become the basis for diversion, but they come with administrative, funding, and manpower challenges. Pill take-back days are labor intensive because of federal and state laws that require the presence of on-site law enforcement when drugs are being collected and as they are transported for incineration. Another lesson learned from pill take-back days is that not only is sponsorship precarious, but so is identifying and maintaining an incineration facility certified by the Environmental Protection Agency (EPA) to receive shipments of collected drugs. Last year, the only facility available in the state would no longer accept pill take-back day shipments and the Drug Enforcement Administration (DEA) had to transport collected drugs to a facility in Alabama.

As a supplement to pill take-back days, permanent pill drop boxes are now located at more than 100 sites in NC. The SBI worked with OMD and Project Lazarus to have secured pill drop boxes installed in many police departments throughout the state. The challenges often continue after permission is secured because maintenance is labor intensive and not all officers assigned to monitoring and emptying the boxes are convinced that this is an appropriate law-enforcement activity in light of perennial restrictions on manpower. For example, the drop-box in Chapel Hill must be emptied at least every 2 weeks, requiring three to four officers a minimum of 1.5 hours to complete the job. The time and manpower commitment of maintenance and drug disposal lacks financial support. This has caused some agencies to consider removing the boxes. However, diversion control is an integral part of overdose prevention.

The Intervention-based (“Top-down”) Components of the Project Model: Addiction Treatment.

Dr. Ashwin Patkar, Medical Director of Duke Addictions Program, Professor of Psychiatry, Duke University School of Medicine, and technical consultant for the Chronic Pain Initiative (CPI), CCNC, describes the substance use disorder treatment spoke of the Project Lazarus Model.

LESSON LEARNED: Engaging and retaining patients with addiction in treatment, rather than a punitive approach of discharge, is an important practice in overdose prevention.

Patients with chronic pain often present with comorbid conditions. Substance use disorders (SUDs) are some of the more challenging

conditions that significantly escalate the difficulties faced by medical care providers, behavioral health managers, families, and communities. The Project Lazarus model identifies two spokes, 1) harm reduction and 2) the provision of adequate community-based addiction treatment as key safety nets in any overdose prevention program. This is critical because overdose risk is higher among patients who suffer from chronic pain and who also have a history of substance use disorders, but are not in treatment. As an example, 2 weeks ago a 24 year-old patient who has been abstinent from opioids and on buprenorphine and naloxone treatment supplemented by weekly counseling, was contacted by one of his classmates over the weekend to share his Suboxone because he (the friend) had relapsed to heroin. The patient advised him to seek treatment through local resources. The next message he heard was that his classmate had overdosed and died.

One objective for the addiction treatment component of Project Lazarus is to improve evidence-based clinical practice for providers treating chronic pain patients with high risk of addiction to or misuse of prescription opioids. Two goals exist: (1) to improve patient care and safety and (2) to ensure that providers are following state and federal guidelines regarding responsible opioid prescribing. This included providing a model CPI tool kit that included templates for patient agreements and informed consent and risk assessment and stratification using standardized instruments, and training providers to conduct brief intervention for patients based on the Screening and Brief Intervention and Referral to Treatment (SBIRT) models. To ensure registration with NC's prescription drug monitoring program (the CSRS), the necessary forms were made available at training programs and prescribers were also encouraged to register. (The recent changes that allow providers to delegate authority for PMP access to another person on the clinical care team has been useful for registration.)

One objective for the addiction treatment component of the Project Lazarus model is to improve pain management for patients with chronic pain who have a high risk for addiction to diverted opioids or the misuse of prescribed opioid analgesics. This can be done by routinely and systematically screening all pain patients for signs and symptoms of addiction, and when present, by providing concurrent substance use disorder treatment. Some of the evidence-based interventions used as a doctor in a medical practice and taught as a technical expert in addiction medicine for CCNC are discussed below as it implements Project Lazarus. Lessons learned from these endeavors are also shared below.

The steps involved in the advocacy of addiction treatment for patients who need concurrent treatment for chronic pain *and* substance use disorder(s) often start in the ED or in the primary care provider's clinic, long before patients are prescribed opioid analgesics, abuse

LESSON LEARNED: Many practitioners may be reluctant to screen for indices of substance use disorder(s) using the SBIRT model when treating pain patients with opioid analgesics. Their reluctance in referring patients found at risk of an overdose is often based on their inability to identify local and affordable resources for behavioral health management and substance use disorder treatment.

their pain medication, or have diverted opioids or other substances. The CPI toolkits developed by CCNC and Project Lazarus provide guidelines for primary care practitioners, ED physicians, and Medicaid case managers about how to routinely screen patients being followed for chronic pain (and are candidates for prescribed opioid analgesics). The screening secures a lifetime history of the misuse or abuse of prescribed or diverted opioids, by means of SBIRT or similar models. This approach was promoted and

discussed at length during all of the Project Lazarus medical care provider training programs. The consensus of participants was that the SBIRT requirement to provide brief interventions or to refer at-risk patients for additional screening was more challenging than the time and personnel required to administer and interpret the screening tools. The CCNC network addressed this problem by creating and distributing lists of local behavioral health management and substance use disorder treatment resources within the area, and by developing a monthly clinical case conference call for network providers with medical care providers who practice in both the local CCNC network and in pain and addiction specialists. Practitioners can discuss up to three of their challenging cases with the specialists on the call. Participants found the recommendations helpful, especially regarding pharmacological management.

Working to change medical practice behavior has been more effective at the systems than at the individual level. An example is the

LESSON LEARNED: Focusing on system wide change in major health systems that employ several physicians is more cost effective than working with individual physicians.

development of an Opioid Safety Task Force at a local hospital system with representatives from various disciplines. The recommendations regarding integrating data from the state PMP with new hospital electronic health records as a framework for several elements of Project Lazarus, have been accepted by this key hospital committee and are likely to be implemented. This does not mean that individual practitioner level efforts should be stopped; instead, the two approaches can be complementary.

LESSON LEARNED: The inadequate supply of providers licensed to prescribe buprenorphine for Medicaid patients is frequently not due to the 30 eligible patients/100 patient limit, but to the billing preferences of its providers that only accept fee-for-service, i.e., cash only patients or those with commercial insurance.

Another step is to address patients' (and non-patients') limited access to substance use disorder treatment. The focus was on increasing

the number of office-based buprenorphine prescribers, in particular primary care practices that are managing chronic pain patients and coordinating links between buprenorphine providers and provision of psychosocial treatment and referral to opioid treatment programs (methadone clinics). A pilot project was initiated for injectable naltrexone to be used in appropriate patients and through collaborative work with large outpatient practices, models of integrated care are being developed to manage depression, anxiety, and PTSD. Some of the strongest challenges were in making buprenorphine treatment available to publicly funded patients. Large systems often have less than five primary care providers who prescribe buprenorphine. Additional barriers include the age-old biases of having "difficult" SUD patients in practice and the perception of methadone being "as bad and addictive as heroin."

One work-around to the inadequate resources for SUD treatment, was to help private nonprofit or for-profit behavioral health groups that were already treating publicly funded psychiatric patients, get their providers certified for buprenorphine treatment. Efforts were successful with groups in the urban area served. However, services in the more remote areas still remain a challenge. A centralized referral and appointment system was developed with managed care organizations (MCOs) so Medicaid patients seeking buprenorphine could call the MCO hotline and immediately make an appointment with a provider through central scheduling. Co-located and reverse co-located models of integrated care are also being developed so primary care providers have psychiatric and counselor back up to prescribe buprenorphine.

Naloxone is not only a standard of care in pain management, but an adjuvant therapy for substance use disorder treatment. Thus, including the co-prescribing of naloxone to patients being treated with an opioid pain medication is a natural fit for the addiction treatment advocacy spoke in the Project Lazarus model.

LESSON LEARNED: Integrating co-prescriptions of naloxone and opioid analgesics into the clinical practice of pain management is more difficult than community based distribution of naloxone to active opioid users and to those who may witness an overdose, such as family members, first responders, and law enforcement officers.

Despite the favorable changes to NC law that provides civil and criminal immunity to practitioners who prescribe naloxone, and to the public who use naloxone in good faith to reverse an opioid overdose, the dissemination of Project Lazarus intranasal naloxone kits has been slow and variable. Many factors have to do with each link in the chain, starting from prescribers, to payers, to pharmacies, and finally to patients, with the cost of the kit ranging from 15–30 dollars.

In the medical practice, a dummy kit is shown to high-risk patients and their family members and strong recommendations are made for buying it, similar to the analogy of buying a fire extinguisher for the home. To date, there are two examples of patients who reported successful uses of the naloxone from the Project Lazarus kit. One gave hers to a friend's family; the friend, an active user, overdosed at home.. The second kit was used by a patient at a dorm party at college where a student overdosed.

Currently, Project Lazarus naloxone kits and the naloxone formulated for intranasal use have to be purchased (or acquired) separately. One way to increase the availability of naloxone kits would be for each of the 14 CCNC networks to purchase the kits and naloxone vials, assemble them along with the educational material, and make them available at local pharmacies or clinical offices.

In conclusion, providing treatment for substance use disorders, especially for opioid addiction, is an essential component of the Project Lazarus model. At least locally, it was easier to implement in locations where existing chronic pain and addiction specialist already existed. Working closely with the CCNC network and using their infrastructure helped greatly. However, challenges remain for populations where access to specialist care is minimal and for populations with limited or no medical coverage. This issue will have to be dealt with at a legislative level for full and effective implementation of the addiction treatment spoke of Project Lazarus.

Conclusions

This white paper presented the lessons learned from several years of experience implementing the Project Lazarus model throughout North Carolina. Each of the various strategies included in the model's hub and spokes, including the difficulties encountered relative to each. Some of these difficulties have been resolved, while others continue. One of the most important lessons learned is that both sets of strategies are necessary to achieve goals, and that both take considerable time, resources, and patience to implement successfully. The work will require continued attention if the devastating epidemic of opioid overdose and abuse are to be reduced in the state. The Project Lazarus model will continue to depend on a successful collaboration that involves multiple sectors of the community, including coalitions, special interest groups, hospitals, medical providers, pharmacies, and law

enforcement. In the absence of this collaboration, which depends on the good will of all, collective efforts will likely fail. This simply cannot be allowed to happen: the stakes in terms of human lives are much too high.

This paper shares the findings of the lessons learned by the presenters for the first and second components of the **Implementing Project Lazarus in North Carolina: Lessons Learned from the Project Lazarus Model webinars** which are posted on the NC Injury Free website (<http://injuryfreenc.org/injury-topics/prescription-drug-overdose/>). **Part 1: The Community-Base (Bottom-Up) Components of the Project Lazarus Model** was broadcasted on May 11, 2015. **Part 2: The Intervention Based (Top-Down) Components of the Project Lazarus Model** was broadcasted on June 29, 2015. All may be quoted, but the editors of the white paper and the webinar presenters hope that all such materials will be appropriately referenced.