

Project Lazarus: Community-Based Overdose Prevention in Rural North Carolina

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Abstract

Background. In response to some of the highest drug overdose death rates in the country, Project Lazarus developed a community-based overdose prevention program in Western North Carolina. The Wilkes County unintentional poisoning mortality rate was quadruple that of the state's in 2009 and due almost exclusively to prescription opioid pain relievers, including fentanyl, hydrocodone, methadone, and oxycodone. The program is ongoing.

Methods. The overdose prevention program involves five components: community activation and coalition building; monitoring and surveillance data; prevention of overdoses; use of rescue medication for reversing overdoses by community members; and evaluating project components. Principal efforts include education of primary care providers in managing chronic pain and safe opioid prescribing, largely through the creation of a tool kit and face-to-face meetings.

Results. Preliminary unadjusted data for Wilkes County revealed that the overdose death rate dropped from 46.6 per 100,000 in 2009 to 29.0 per 100,000 in 2010. There was a decrease in the number of victims who received prescriptions for the substance implicated in their fatal overdose from a Wilkes County physician; in 2008, 82% of overdose decedents received a prescription for an opioid analgesic from a Wilkes prescriber compared with 10% in 2010.

Conclusions. While the results from this community-based program are preliminary, the number and nature of prescription opioid overdose deaths in Wilkes County changed during the intervention. Further evaluation is required to understand the localized effect of the intervention and its potential for replication in other areas.

Key Words. Overdose; Prescription Monitoring; Opioids; Chronic Pain; Community-Based Research; Surveillance

Introduction

In response to some of the highest drug overdose death rates in the country, Project Lazarus developed a community-based overdose prevention program in Western North Carolina. Wilkes County is one of the largest land mass counties in North Carolina, covering over 700 square miles in the foothills of the Appalachians with a current population of approximately 66,500. Historically, logging, textiles and manufacturing, and cattle and chicken farming have been primary industries. In the 1930s, prohibition brought about moonshine activity; Wilkes is the birthplace of National Association for Stock Car Auto Racing, a sport with an explicit history intertwined with moonshine, suggesting generations of substance misuse and abuse at the margins of the law. With much physically demanding employment, Wilkes has a significant population that suffers the physical consequences of work-related injuries, with a substantial burden of chronic pain. The unemployment rate consistently exceeds the national average and combined with poverty and limited educational opportunities, creates a cycle of socioeconomic depression.

The Wilkes County unintentional poisoning mortality rate (primarily from drug overdoses) is quadruple that of North Carolina's (46.6 vs 11.0 state mortality rate per 100,000

Table 1 Coalitions and organizations involved in community-based response to opioid overdose deaths in Wilkes County, North Carolina

	Entity	Description	Responsibility
1	Substance Abuse Task Force, Wilkes Health Carolinians Council	County-level partnership supporting coalition building for health actions	Raising awareness of overdose problem
2	Chronic Pain Initiative, Northwest Community Care Network	Regional (substate) Medicaid authority, including 70 practices and 58,000 patients in six counties	Clinical education on pain management; policy changes for Medicaid beneficiaries; seed funding for community-based response
3	Wilkes County Health Department	Local health department	Data review and collection; authority for action; meeting facilities
4	Project Lazarus	Nonprofit organization	Coordination of efforts between organizations and individuals; school-based education; community outreach; promotion of drug treatment; evaluation

population per year in 2009) and due almost exclusively to prescription opioid pain relievers [1]. Top opioids implicated in deaths include fentanyl, hydrocodone, methadone, and oxycodone; heroin is rarely suspected in overdose deaths. The average age of death is in the late 30s, and decedents have considerable comorbid health conditions, including respiratory, circulatory, and metabolic disorders. Those who are dying are county residents who use opioids for both medical and nonmedical reasons and exceeded their physiologic tolerance, either directly or in combination with other licit or illicit substances [2,3].

Decades of studies about drug misuse and overdose within North Carolina have contributed to a nuanced understanding of the nature of deaths [2,4–9]. In a study of Medicaid beneficiaries who died of a methadone overdose, state health department researchers found that in the 34 days prior to death, 30.7% of decedents had codes for methadone maintenance for addiction, while 57.7% had codes for outpatient dispensing, most likely for chronic pain [10]. These findings were similar to an earlier study conducted by a Project Lazarus staff member in conjunction with the Centers for Disease Control and Prevention [9]. A study of a pain clinic at a North Carolina academic center revealed that 32% of patients exhibited behaviors associated with misuse of pain medications [11]. Taken together, these and other local data form the basis for designing the Project Lazarus prevention strategies.

Drawing upon successful public health campaigns in injury prevention, Project Lazarus created a model for preventing prescription opioid overdose deaths that includes the following five components: community activation and coalition building; monitoring and surveillance data; preven-

tion of overdoses; use of rescue medication for reversing overdoses by community members; and evaluating project components. The last four steps operate in a cyclical manner, with community advisory boards playing the central role in developing and designing each aspect of the intervention.

At the center of Project Lazarus is the understanding that communities are ultimately responsible for their own health and that active participation from a coalition of community partners is required for a successful public health campaign. The community-based organizations primarily responsible for responding to the overdose problem in Wilkes County are presented in Table 1. Community activation describes the concrete actions required to bring communities together to develop a health promotion scheme and to build long-term social capital. The Project Lazarus model is based on previous research on community activation for health promotion, which indicates that the following organizations are the most important for successful public health campaigns: health department, schools, governmental agencies, hospitals, primary care clinical practices, churches, and newspapers; the following organizations have also been identified as having a role in health promotion in nonurban areas: television stations, health-related nonprofits, substance abuse treatment centers, and colleges [12].

The overdose prevention activities and their years in operation, as designed by the community coalitions, are outlined in Table 2. These “bottom-up” interventions were designed and developed by local individuals, agencies, and organizations that leveraged existing resources or raised awareness and funds for new programs. The role of Project Lazarus has been to coordinate these efforts,

Table 2 Activities and timeline of community-based prevention of overdose

No.	Activity	Years of Operation
<i>Community organization and activation</i>		
1	Town hall meetings	2006–present
2	Specialized task forces	2005–present
3	Community-based leadership	2005–present
4	Coalition building	2005–present
5	“Managing Chronic Pain” tool kit assembled	2007–2008
<i>Prescriber education and behavior</i>		
6	One-on-one prescriber education on pain management (“academic detailing”)	2008–2010
7	Continuing medical education sessions on pain management	2008–2010
8	Licensing actions against prescribers by state medical board	2008
9	Promotion of CSRS	2007–present
<i>Supply reduction and diversion control</i>		
10	Hospital ED opioid dispensing policy modified (e.g., limits on amount dispensed at once, required check of CSRS for hospital ED admissions)	2008–present
11	Unused medication take-back events by sheriff and police departments, with support from DEA and SBI	2009–present
12	Fixed medicine disposal sites at law enforcement offices	2011
13	Hiring and training of drug diversion specialized law enforcement officers	2009–present
<i>Pain patient services and drug safety</i>		
14	Medicaid policy change: mandatory use of patient–prescriber agreements and pharmacy home	2010
15	Support groups for pain patients	2008–2009
16	ED case manager for Medicaid beneficiaries with chronic pain	2008–present
17	Vetting of local pain clinics and facilitation of specialized pain clinic referrals	2008
<i>Drug treatment and demand reduction</i>		
18	Drug detox program	2000–present
19	Negotiation and support for opening of satellite office-based drug treatment clinic (buprenorphine)	2009
<i>Harm reduction</i>		
20	Naloxone prescription	2010
<i>Community-based prevention education</i>		
21	School-based education, including pledge cards	2009–present
22	Red Ribbon campaign—warnings not to share attached to dispensed prescription packages	2010
23	Billboard containing message against sharing medications	2010
24	Presentations at colleges, community forums, civic organizations, churches, etc.	2007–present
25	Radio and newspaper spots	2006–present

CSRS = Controlled Substances Reporting System; DEA = Drug Enforcement Administration; ED = emergency department; SBI = State Bureau of Investigation.

including developing strategic and action plans, training community organizers, and raising awareness of the overdose problem. This model operates in contrast to other “top-down” public health approaches in which interventions are devised by expert advisory boards and health authorities, funded centrally, and subsequently, adopted at the local level. There are advantages and limitations to both approaches. In this article, we describe a community-based intervention in an Appalachian county with high overdose rates and provide qualitative process observations and preliminary quantitative results.

Interventions

Development of Overdose Prevention Efforts

Table 2 lists interventions to prevent overdose fatalities in Wilkes County. It is beyond the scope of this article to provide details of each intervention, but we highlight a handful later. Overdose prevention efforts were proposed by coalition members and developed and implemented by responsible parties through their professional responsibilities or by volunteers. Of particular interest, two of the

central efforts of the Chronic Pain Initiative (CPI) have been to educate primary care physicians in managing chronic pain in the outpatient setting and in safely prescribing opioid medications. Both were done largely through the creation of a physician's tool kit for chronic pain management and face-to-face meetings with physicians.

Additional prevention efforts were designed by other organizations in Wilkes County. For example, policy changes in the hospital emergency department (ED) were implemented by hospital administrators. The Northwest Community Care Network (NCCN), the region's Medicaid authority, and hospital system jointly placed a case manager in the ED to coordinate care for chronic pain patients who are on Medicaid or who are uninsured, including active follow-up for referrals to primary or subspecialty care for treatment of the underlying cause of their chronic pain. In a pilot project by the NCCN, patient-prescriber agreements were mandated for a subset of chronic pain patients on Medicaid in Wilkes County. As part of their agreement, patients were locked into using a single pharmacy and single prescriber for all opioid therapy, and increased linkages were set up to facilitate communication between physicians. This system was intended to place responsibility for prescribing opioids in the hands of a single physician, who would be aware of all the concomitant medications and patient history.

Monitoring Data Sources

Data from four state government-run health sources constitute the core monitoring elements that are used to describe and characterize overdoses: ED visits for substance abuse and accidental poisonings, via North Carolina's mandatory syndromic surveillance infrastructure known as the North Carolina Disease Event Tracking and Epidemiologic Collection Tool (NC DETECT) [13]; outpatient-dispensed controlled substances from the Controlled Substances Reporting System (CSRS or "prescription monitoring program"); fatal accidental poisonings from the North Carolina Office of the Chief Medical Examiner; and vital statistics from the North Carolina State Center for Health Statistics. Access to the data was individually negotiated by Project Lazarus staff and cleared through respective ethical review mechanisms.

Evaluation of Interventions

Given the complex relationships among the forces at the community level that impact overdose mortality, and given the multifaceted response, it is not feasible to ascertain the individual causal impact of each intervention in isolation. A rigorous evaluation is under way, which emphasizes assessment and measurement of potential confounders in Wilkes and surrounding counties. At the time of preparation of this manuscript, only crude (unadjusted) rates for Wilkes County were available. Until adequate assessment of and adjustment for potential confounders is conducted, these data should be interpreted with caution. A news report suggested a decline in overdose mortality in Wilkes County in 2010 citing medical

examiner data, but no thorough evaluation has been conducted to date [14]. However, an evaluation of the CPI has been completed by researchers at Wake Forest University and is being published separately [15].

Evaluation of Program Components

Community Activation and Coalition Building

As a result of the heightened community awareness, activation, and community-building activities, many organizations are now engaged in responding to the overdose epidemic in Wilkes County. A central community organizer holds positions as part of Project Lazarus, the CPI, and the Substance Abuse Task Force and is responsible for coordinating overdose prevention efforts and minimizing duplication. Developments from one group are disseminated to others, and major community-wide decisions are brought before each of the advisory boards. The community boards have ongoing engagement in the prevention efforts in Wilkes as they review and evaluate results of intervention, making adjustments to program elements when necessary. In this manner, the community boards are active in dictating the direction of change that they would like to see and have shown sustainability beyond the initial charges when they were convened.

Monitoring and Surveillance

Preliminary unadjusted data from Wilkes County suggest that the overdose death rate has dropped from 43 per 100,000 in 2008 to 29 per 100,000 in 2010 (Figure 1). While it is too early to draw a conclusion from these numbers alone, they are indicative of a response from community-based prevention efforts; Wilkes County did not see the increases in overdose deaths that nearly every other county in North Carolina experienced.

Supporting the idea of a community-level effect, we have seen a decrease in the number of fatal overdose victims who received prescriptions for the substance implicated in their overdose from a Wilkes County physician. Specifically, in 2008, 82% of decedents had received a prescription for an implicated substance from Wilkes prescribers, dropping to 10% in 2010.

Prevention of Overdose

Various organizations have contributed to efforts to prevent overdoses in Wilkes County. A few indicators are presented later. However, it should be kept in mind that many other efforts have paralleled these beyond the confines of clinical practice.

Physician education has been conducted by the medical director of the County Health Department, who visited half the physicians registered with the Drug Enforcement Administration in the county, representing 70% of office practices, a strategy that others have called "academic detailing." Starting in 2007, the CPI also began work on a tool kit for local primary care prescribers, making it avail-

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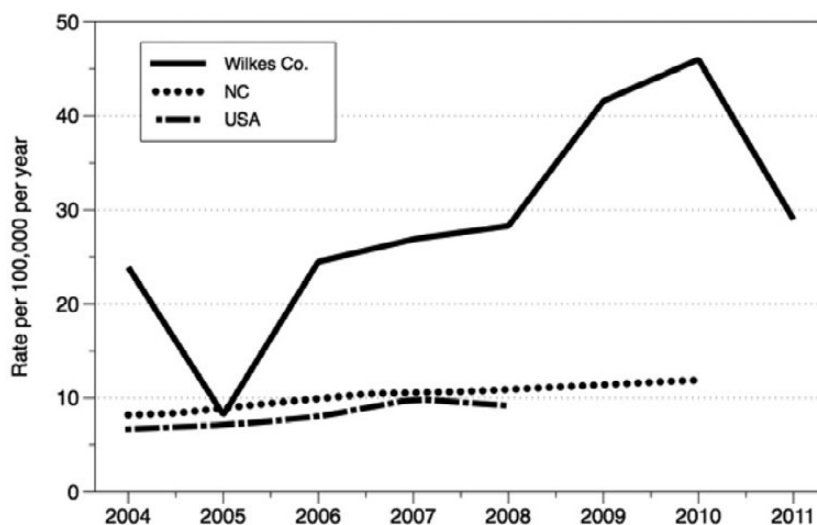


Figure 1 Comparison of U.S., North Carolina, and Wilkes County overdose mortality data.

able to all prescribers. The tool kit contains pain management guidelines, opioid risk assessment tools, “universal precautions” for opioid prescribing [16], a sample patient–prescriber agreement (“pain contract”), defensive prescription writing, patient education materials, and screening, brief intervention, and referral to treatment (SBIRT) modules [17]. While other tool kits were nationally available at the time CPI started [18–20], the year-long process of developing a custom tool kit for the local context contributed significantly to community mobilization and allowed for the development of strong bonds between organizations and individuals involved in the response. The promotion of the CSRS was emphasized by providing forms and support to enable clinicians to register to use the system at all events where clinicians attended, along with continued encouragement and follow-up contacts. With 70% of prescribers registered, Wilkes County has by far the highest rate of utilization of the CSRS in the state (average 20%) [21].

Data from Wilkes County indicated that more than half of overdose deaths occurred in the home setting, where emergency medical care was never called because bystanders did not recognize that the signs and symptoms they were witnessing meant that their loved one had taken a potentially lethal overdose. In other cases, medical services were not activated soon enough, and in this large land area county, emergency services were unable to reach the victim in time to reverse the overdose. Even in communities with the most aggressive and innovative drug overdose prevention programs, not everyone hears or comprehends overdose risk messages, and not everyone is willing or able to abstain from using pharmaceutical opioids for nonmedical purposes. Likewise, not everyone with inadequate pain control understands the dangers inherent in making their own medication adjustments, taking other people’s medicines, or combining their medicines with other substances that could increase the chance of overdose. A rescue response is necessary because overdoses are still going to occur despite the

best prevention efforts. Responsible public health programs should have services for the community that openly acknowledge the difficulties in changing behavior and set realistic time frames for effects of an intervention to take effect.

The Project Lazarus take-home naloxone provision model addresses the need for rescue and works as follows. A Wilkes County resident sees a physician for routine medical care. The physician, who has been trained by Project Lazarus, identifies the patient as a naloxone priority patient based on criteria for overdose risk (Table 3). The 13 priority groups and risk factors were derived from a review of the known etiology of opioid-induced respiratory depression and clinical insight. When patients agree to participate in Project Lazarus, they watch a 20-minute DVD in the physician’s office. The video covers patient responsibilities in pain management, storage, and disposal of opioid medications, recognizing and responding to an opioid overdose and options for substance abuse treatment. Project Lazarus participants then go to a pre-arranged community pharmacy and pick up a free naloxone kit. The messaging in Project Lazarus materials does not dwell on the differences between “legitimate” and “illicit” users of opioids but rather presents straightforward information that can be used to prevent an overdose fatality.

In response to high use of episodic emergent care to treat chronic pain in Wilkes county, revised policies for dispensing narcotics in the ED at the only hospital in the county were codified and posted prominently in the waiting area in the hope of deterring drug-seeking behaviors. The new policies state that the CSRS must be accessed for all patients receiving an opioid and provides for reprogramming ED software to lower the default number of units of opioids to be dispensed (nine vs 50 in the native software). Follow-up appointments are made for the next working day for referral to a pain treatment expert or primary care doctor. While the volume of patients in the ED decreased

Table 3 Project Lazarus naloxone priority groups and risk factors for opioid-induced respiratory depression

Naloxone priority groups and risk factors for opioid overdose

Recent medical care for opioid poisoning/intoxication/overdose
Suspected or confirmed history of heroin or nonmedical opioid use
High-dose opioid prescription (≥ 100 mg/day morphine equivalence)
Any methadone prescription for opioid naive patient
Recent release from jail or prison
Recent release from mandatory abstinence program or drug detox program
Enrolled in methadone or buprenorphine detox/maintenance (for addiction or pain)
Any opioid prescription and known or suspected:
Smoking, COPD, emphysema, asthma, sleep apnea, or other respiratory system disease
Renal or hepatic disease
Alcohol use
Concurrent benzodiazepine use
Concurrent antidepressant prescription
Remoteness from or difficulty accessing medical care
Voluntary patient request

ED = emergency department; COPD = Chronic obstructive pulmonary disease.

initially because of this policy, the nature of complaints shifted over time to more serious cases that needed emergency attention, leading to higher reimbursement rates and improved patient satisfaction scores.

Health Economics Assessment

A complete health economics analysis of community-based overdose prevention is beyond the scope of this article, but preliminary numbers are available. According to the Agency for Healthcare Research and Quality, the average cost of an inpatient hospitalization for opioid poisoning in North Carolina in 2008 was \$16,970; Medicaid, Medicare beneficiaries, and the uninsured accounted for 74.5% of these stays [22]. The estimated loss in productivity for each poisoning is \$18,704 [23]. In terms of expenditures in Wilkes County, physician education and partial community mobilization efforts resulted in approximately \$25,000 per year of salary time for two part-time employees. The total operating budget of Project Lazarus was approximately \$220,000 over the 15-month period ending in December 2010, including purchase of naloxone, evaluation, conference attendance, travel, overhead expenses, and salaries for seven part-time employees. Many other organizations and local businesses contributed resources in terms of staff time and in-kind donations, but exact monetary contributions have not been determined. Even if

Project Lazarus prevented 18 inpatient hospitalizations due to opioid poisoning, a favorable cost : benefit ratio would be achieved; about half that many would have to have been avoided if taking loss of productivity into account. However, these estimates should be interpreted carefully as they do not constitute a rigorous analysis, and are intended to serve as a rough estimate for other areas considering implementation.

Lessons and Potential Future Applications of Findings

Just as the physiological and anatomical bases for pain and addiction share common neurophysiological pathways, the community-level response to prescription opioid use problems must address pain and abuse/addiction simultaneously. There may be legal and policy-level justifications for drawing distinctions between medical and nonmedical users of prescription opioids. However, our experience has been that in a small, rural community, finely delineating two groups ("legitimate" vs "illicit" or similar constructs) is a time-consuming task with limited returns. It is a practice that exacerbates stigma, blocking those who are at the greatest risk for overdose from receiving prevention messages and an opioid overdose antidote, a practice that is consistent with other medical conditions and medication regimens, such as diabetes. The extreme ends of the spectrum of misuse and abuse behaviors are easiest to identify, e.g., large-scale doctor shoppers or physicians prescribing for profit to terminal pain patients in hospice. Our investigations of deaths in Wilkes County have revealed that the vast majority of individuals who overdose fall into a gray zone between these outlier scenarios. The reality of living in the community where you work has led us down a pragmatic path of simultaneously blending supply reduction, demand reduction and harm reduction strategies.

Researchers at Wake Forest University have completed an evaluation of the elements in the CPI tool kit managing chronic pain [15]. Based on the results of evaluation, the chronic pain tool kit is being revamped to highlight the tools that doctors found most useful (e.g., patient-prescriber agreement) and modifying those perceived to be less useful. The evaluation did find that physicians' prescribing behaviors changed after exposure to the peer-mediated education and after receiving the tool kit. Encouraged by these findings, the hospital ED has requested that a tool kit be created for treating pain in emergency settings. Patients also responded that the prescriber-patient agreement and other explicit policies of the CPI helped them understand their care better, setting expectations that both physicians and patients could meet.

The public sometimes expects law enforcement officials to single-handedly address the drug overdose problem in a community. Project Lazarus recognizes that law enforcement has an important role to play in reducing diversion of prescription opioids but also that a community-wide approach includes, but does not rely solely on, law

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enforcement. Project Lazarus helped local law enforcement departments hire and train two officers dedicated to cases involving the criminal diversion of prescription drugs. These officers have empowered the law enforcement community to take a more proactive role in responding to the overdose problem, including organizing medication “take-back” events and dedicated disposal sites.

The response to overdose deaths in Wilkes County has been multifaceted and phased in over time. Some of the intervention elements may have immediate effect, whereas changes in physicians’ and patients’ behaviors can take a long time to be realized, and the impact on the mortality rate may not be apparent for even longer. In terms of evaluations, linking the mortality data with the CSRS can reveal associations that require modification of an intervention to avoid unintended consequences. It was recognized that criminal prescribing and diversion may be contributing to the greater than expected overdose rates in Wilkes County, but the association was not always clear. For example, in December 2008, the North Carolina Medical Board suspended the license of a physician who was deemed to have been prescribing controlled substances negligently after investigation by undercover law enforcement operations. Prior to the suspension, there was suspicion that the physician was prescribing improperly; however, this physician’s prescriptions were not routinely implicated in overdose deaths. It was only after the suspension that individuals under his care started dying of overdoses, probably due to a disruption in opioid tolerance. Other managers of practices in the county did not want to handle patients who had been under this physician’s care as they were perceived to be problem patients at best and addicted at worst. It became evident that supply reduction practices in the absence of demand reduction and harm reduction could paradoxically *increase* overdoses, a finding consistent with literature on illicit drugs [24,25]. In response, Project Lazarus negotiated and supported the opening of a satellite outpatient treatment program in 2009, with more than 250 opioid-dependent patients currently enrolled on buprenorphine treatment, a demand reduction approach documented to have reduced opioid overdose deaths and drug-related crime in other countries [26].

Hypothetical concerns with providing naloxone to patients and drug users have been raised. One concern with pre-hospital administration of naloxone is the return of respiratory depression. During a 5-year period in San Diego, 998 out-of-hospital patients received naloxone (primarily due to heroin overdose) from emergency medical services and refused transport, against medical advice. Reviews of medical examiner records found no instances of individuals dying of opioid poisoning within the 12 hours following naloxone administration [27,28]. Further supporting these observations, it is well-established in animal models that opioid tolerance is place-dependent, and there is reason to believe that return of opioid depression after an initial administration of naloxone may be different in hospital and community settings [29,30]. Another hypothetical concern

is risk compensation, whereby individuals take greater risks because of the presence of a safety mechanism. Studies evaluating the decade of naloxone distribution to heroin users in the United States have not revealed convincing evidence of risk compensation [31–35]. In cities with large-scale naloxone prescribing and dispensing programs for heroin users, opioid overdose mortality has consistently decreased after implementation, suggesting that naloxone distribution programs do not lead to increases in overdose deaths [36–38].

The North Carolina Medical Board raised these and other concerns during a public hearing on Project Lazarus in November 2007. After questioning and deliberation, the board issued the following position statement: “The Board has reviewed and is encouraged by, the efforts of Project Lazarus, a pilot program in Wilkes County that is attempting to reduce the number of drug overdoses by making the drug naloxone and an educational program on its use available to those persons at risk of suffering a drug overdose. The prevention of drug overdoses is consistent with the board’s statutory mission to protect the people of North Carolina. The Board therefore encourages its licensees to cooperate with programs such as Project Lazarus in their efforts to make naloxone available to persons at risk of suffering opioid drug overdose” [39].

Summary

The five-component strategy created by Project Lazarus is centered around community activation and a strong coalition of partners who have an active interest in preventing prescription overdose deaths [3]. It capitalizes on using existing data sources to provide perspectives on fatal and nonfatal overdoses and serves as a mechanism to evaluate interventions. The multiple levels of prevention efforts and community-based education are intended to reach medical care providers as well as pain patients and non-medical drug users without exacerbating stigma. School-based prevention education targets vulnerable populations and aims to shift general patterns of substance abuse. The provision of take-home naloxone acknowledges that prevention efforts can fail or take years to have effect and that overdose deaths can be prevented in the community. Finally, evaluations of specific interventions can provide input on how to improve the services. The overall impact is under evaluation, but initial results suggest that the Project Lazarus model of enhanced and coordinated empowerment in responding to overdoses among law enforcement, physicians, and pain patients may be making headway in reversing Wilkes County’s epidemic of drug overdoses. Target communities for replicating the Project Lazarus model include those with high-prescription opioid unintentional poisoning rates and some degree of community awareness and coalition-building capacity. The presence of a motivated community organizer, support from the medical establishment, and strong data utilization practices are key components for replication.

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