U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY AND COMMERCE

Hearing on "Examining the Growing Problems of Prescription Drug and Heroin Abuse: State and Local Perspectives."

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SUMMARY: Project Lazarus is a public health, nonprofit organization established as a response to extremely high mortality rates due to prescription medications in Wilkes County, NC, which had the third highest overdose death rate in the nation in 2007; 46.6 per 100,000 pop., according to the Centers for Disease Control and Prevention. In order to effectively target overdose deaths in Wilkes, the Project Lazarus Model, a public health model based on the twin premises that prescription medication overdose deaths are preventable and that all communities are responsible for their own health, was devised and implemented for prevention, intervention, and treatment.

- *Prevent opioid related sedation and drug overdoses*
- *Present responsible pain management*
- *Promote substance use treatment and support services*

The overdose mortality rate decreased to 29.0 per 100,000 pop. in 2010 and to 14.4 per 100,000 pop. by 2011 after implementation of the Project Lazarus Model. This indicates a 69% drop within two years. Wilkes scripts related to overdose in 2008 were at 82% and decreased to 0% in 2011, substance use ED visits were down 15.3 %, opioid treatment program admissions were at 0 in 2010, but in 2014 were at 400+, and the community widely began accepting medication assisted treatment to the extent that local Wilkes churches are supporting individuals in treatment.

After the success in Wilkes, Project Lazarus began expanding statewide into all 100 NC counties. With the expansion through collaborative partners and funders (Kate B. Reynolds Trust, NC Office of Rural Health, Community Care of NC, Mountain Area Health Education

Center, and Project Lazarus) counties statewide are implementing the Project Lazarus Model to address the issues surrounding prescription medications. Once a coalition is established and completed the necessary Project Lazarus training, communities will be able to operate and sustain their coalition based on the Project Lazarus Model.

To date, Project Lazarus has been involved in the implementation of legislation, programs, and county coalitions across NC, various US community and state projects (FL, IN, KY, MD, MI, NJ, NM, OK, PA, TN, UT, VA, WV, and others), Tribal Groups, and the US Military (Operation OpioidSafe, which reduced overdose deaths among soldiers within the Warrior Transition Unit from 15 out of 400 to 1 out of 400 in first year of implementation).

Project Lazarus enables overdose prevention by providing training and technical assistance to create and maintain community coalitions, as well as capacity building for existing coalitions in the foundation of locally tailored drug overdose prevention programs and connecting coalitions to state and national resources. Project Lazarus also assists in the provision of access to naloxone, the overdose rescue medication, to those at risk of an overdose or to family and friends who have a loved one at risk. Lazarus Recovery Services has been launched to provide community based peer support for those currently using or seeking recovery and/or treatment.

The Project Lazarus Model provides a bottom-up approach coupled with top-down policy, practice, and initiative changes, including promotion and support from State / Federal levels.

I. **Public Awareness** is important because there are widespread misconceptions about the risks of prescription medication misuse and abuse. It is crucial to build public identification of prescription medication-related respiratory depression causing overdose as a community issue and that overdose is common, as well as preventable.

- Identify issue at local level
- Broad-based outreach- all population groups

Federal and State programs for awareness by ONDCP, SAMHSA, HRSA, Offices of Rural Health, Department of Health and Human Services.

II. **Coalition Action**- A functioning coalition should exist with strong ties and support from each of the key sectors in the community, along with a preliminary base of community

awareness on the issue. Coalition leaders should have a strong understanding of what the nature of the issue is in the community and what the priorities are on how to address it.

- Community Sectors- answering the questions, providing best practice solutions
  - Why am I needed?
  - What do I need to know?
  - What needs to be done?

Federal and State initiatives by ONDCP and SAMHSA with Drug Free Community Support Program grants, SAMHSA with Strategic Prevention Framework-Partnerships for Success (SPF-PFS) grants, and Block Grant Funding.

III. **Community Education** efforts are those offered to the general public and are aimed at changing the perception and behaviors around sharing prescription medications and improving safety behaviors around their usage, storage, and disposal.

Prescription Medication: "Take Correctly, Store Securely, Dispose Properly, and Never Share. ™"

IV. **Data and Evaluation** to ground a community's unique approach in their locally identified needs and improve interventions. It is very important to provide local data information in as real time reporting as possible.

Federal CDC and State Public Health working jointly for aligned data analysis and effective reporting. Assistance needs to be provided to states for data collaboration among various state agencies to share the data information in order for local communities to access and evaluate outcomes.

V. **Prescriber Education**-Toolkit is taught through local office lunch-and-learns, CME events, grand rounds, and medical management meetings.

- Key components:
  - Opioids in the management of chronic pain
  - Patient assessment and management
  - Opioid overdose prevention- co-prescribing of rescue medication, naloxone
  - Prescriber & patient education materials, resources, and referral mechanisms
  - Screening forms and brief intervention
  - Use of prescription drug monitoring programs
  - 49 States have prescription drug monitoring programs in various stages of operation or establishing.

SAMHSA has provided the Overdose Prevention Toolkit for best practice for the prescribing community and other sector groups, such as law enforcement and first responders. National organizations are publishing responsible pain practice and prescribing material: AMA, Federation of State Medical Boards, State Medical Boards, Professional Academies, etc.

http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742

FDA has approved medications with labeling indicating abuse deterrent properties that collectively are expected to reduce abuse via intranasal, intravenous, and oral routes. These should be readily available and indicated as preferred in order to further reduce medication manipulation for abuse.

http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bfdfe235-d717-4855-a3c8-a13d26dadede

http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205777lbl.pdf

http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a7658a2d-b7a9-4fb5-8d65-a20ca1b9ad1f

http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b7d23ac2-e776-9f62-3290-c64c2d6eb353

VI. **Hospital Emergency Department (ED) Policies**- it is recommended that hospital ED's develop a system-wide standardization with respect to prescribing narcotic analgesics as described in the Project Lazarus Toolkit for managing patients with pain.

- Embedded ED case manager
- "Frequent fliers" for chronic pain; non-narcotic medication and referral
- No refills of controlled substances
- Use of prescription drug monitoring programs
- Limited dosing (10 tablets)

Emergency Administration Policy changes worked with system wide acceptance and implementation occurring within hospital networks.

VII. **Diversion Control** is supporting and educating individuals on prescription medication: "Take Correctly, Store Securely, Dispose Properly, and Never Share. ™"

- Providing law enforcement, pharmacist, and facility training on forgery, methods of diversion, and drug seeking behavior.
- Supporting and providing medication take back events, and placement of permanent disposal containers within law enforcement, pharmacies, hospitals, and clinics.

DEA provided new policy October 2014 to allow for retail pharmacies, hospital and clinic based pharmacies, long term care facilities, and narcotic treatment programs to begin to take back controlled substances providing further pathways for proper disposal and less medications within communities.

http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf

VIII. **Pain Patient Support**- In the same way that prescribers benefit from additional education on managing chronic pain, the complexity of living with chronic pain makes supporting community members with pain important.

- Proper medication use and alternatives, "Take Correctly, Store Securely, Dispose Properly, and Never Share. ™"
- Alternatives: health and wellness, music, breathing, physical therapies, acupuncture, yoga, exercise, etc.

IX. **Naloxone/Harm Reduction** overdose prevention and intervention-it is a rescue medication for reversing overdose.

- Increasing access to naloxone for community, patients, military and tribal groups, individuals, family members, law enforcement, and first responders is one component of a broader approach to help reduce opioid-related morbidity and mortality.
- Distributing a script that gives patients specific language they can use with their family/caregiver to talk about overdose and develop an action plan, similar to a fire evacuation plan.
- Determined at-risk factors of opioid respiratory depression and overdose if there is a combination of prescription opioids with any of the following:

- Smoking, COPD, emphysema, asthma, sleep apnea, or other chronic respiratory disease
- Renal dysfunction or hepatic disease that may interfere with opioid metabolism or elimination from the body.
- Known or suspected concurrent substance use, including alcohol use
- Concurrent benzodiazepine prescription
- Concurrent anti-depressant prescription
- Recent emergency medical situation for opioid poisoning and/or intoxication
- Suspected history of illicit or non-medical opioid use
- Prescription for a high dosages of opioids
- Methadone prescription (specifically, opioid naïve patients)
- Use of an extended release or long-acting opioid preparation
- Recent release from incarceration
- Recent release from an opioid detox or mandatory abstinence program
- Enrolled in a methadone or buprenorphine detox and/or maintenance program for addiction or pain
- Voluntary request from patient or family member
- Difficulty accessing EMS due to distance, remoteness, etc

Federal ONDCP and SAMHSA have been leading the way for promotion and availability of naloxone to those who are at risk for overdose. It is essential that naloxone be available across all community sectors reaching all those potentially at risk.

In 2014, the FDA fast tracked approval of a new naloxone auto injector device providing a more streamlined availability that is specifically FDA approved for use outside medical settings by

family members or caregivers versus the off-label combination of a prefilled syringe and the application of a nasal atomizer. The traditional draw and inject intramuscular administration remains available as the least expensive and is widely provided heroin using populations, but requires training on preparation and administration. Hindrances remain due to lack of broader acceptance among Medicaid, CMS, and private insurers, though within Department of Defense and Veterans Administration, it is covered. There is a possible increase in funding for naloxone within the 2015/2016 Federal budget that needs to be appropriated.

National medical and law enforcement organizations have published best practice and position statements indicating the need to have and provide naloxone to those at risk of potential opioid related sedation and drug overdose.

Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis.

OPEN ACCESS Alexander Y. Walley assistant professor of medicine, medical director of Massachusetts opioid overdose prevention pilot 1 3, Ziming Xuan research assistant professor 2, H Holly Hackman epidemiologist 3, Emily Quinn statistical manager 4, Maya Doe-Simkins public health researcher 1, Amy Sorensen-Alawad program manager 1, Sarah Ruiz assistant director of planning and development 3, Al Ozonoff director, design and analysis core 5 6

BMJ 2013;346:f174 doi: 10.1136/bmj.f174 (Published 31 January 2013) Zedler, B., Xie, L., Wang, L., Joyce, A., Vick, C., Kariburyo, F., Rajan, P., Baser, O. and Murrelle, L. (2014), Risk Factors for Serious Prescription Opioid-Related Toxicity or Overdose among Veterans Health Administration Patients. Pain Medicine, 15: 1911–1929. doi: 10.1111/pme.12480

Substance Use Disorder/Addiction treatment, especially opioid agonist therapy like methadone, partial agonist buprenorphine treatment and naltrexone, has been shown to dramatically reduce overdose risk and provide for successful recovery. There is not one treatment that works for all, but there are sufficient treatments that work for all and they should be widely available, effectively covered with providers accepting reimbursement.

Unfortunately, access to treatment is limited by a few main factors:

- Acceptability, Availability and Accessibility of treatment options.
- Negative attitudes or stigma associated with addiction in general and drug treatment.
- Limited providers and limits on providers.

Hubbard, Jule. "Local Methadone Clinic Helps Reduce Rx Deaths." The Journal Patriot 12 Mar. 2014. Web. 24 Mar. 2015. <http://www.journalpatriot.com/news/article_dbd0f6e8-aa0c-11e3-8435-001a4bcf6878.html>.

Federal agency SAMHSA providing Grant to various States to increase Medication Assisted Treatment availability. http://www.samhsa.gov/grants/grant-announcements/ti-15-007