Intranasal administration of Naloxone by the EMT-Basic has been proposed by FDNY as a demonstration project for the New York City region. NYC REMAC gave its approved to the proposal on 3/20/07 and passed it on to NYC REMSCO which approved it 3/27/07. It next has to be approved at the state level at SEMAC and SEMESCO meetings to be held May 1st & 2nd. If given all the necessary approvals, the project would be open to all EMS agencies in NYC able to participate and maintain QA requirements. FDNY has indicated it would share its training package with other agencies who would have to supply their own instructors.

Naloxone is a drug used to counter the effects of opioid overdose, for example heroin or morphine overdose. Naloxone is specifically used to counteract life-threatening depression of the central nervous system and respiratory system. It is marketed under various trademarks including Narcan, Nalone and Narcanti. Naloxone is usually injected intravenously for fastest action, acts after about two minutes and its effects may last about 45 minutes. Other routes, including intramuscular injection and intranasal injection (use of a wedge device attached to the syringe to create a mist delivering the drug to the nasal mucosa) are also be utilized, although these are more likely in the prehospital setting. Naloxone has been distributed as part of emergency kits to heroin users and their friends and family, and this has been shown to reduce rates of fatal overdose. Projects of this type are underway New York State, Baltimore, Boston, Chicago, Los Angeles, New Mexico, Philadelphia and overseas in Scotland in 2006.
an estimated 160,000 heroin abusers, and an estimated to be another 40,000 patients enrolled in out-patient methadone programs.

In addition to increased use of illicit substances, the noted increase in heroin purity raises additional concern for accidental overdoses that may present as altered mental status and/or respiratory compromise. Prior to 1988, the average purity of the heroin found in New York City was less than 10%, and more recently has reportedly increased to over 60% purity.

Patients who suffer opioid overdoses may be appropriately treated by ALS providers with opioid antagonists such as naloxone (Narcan), in addition to basic life support maneuvers such as assisted ventilation. In the absence of such ALS personnel, treatment may be limited to ventilatory support, a therapy with potential to provide both benefit (i.e. improved ventilation) and harm (i.e. gastric insufflation, induced emesis).

In calendar year 2006, FDNY data identified 1,112 cases for which BLS arrived on scene first and for whom naloxone was ultimately given upon ALS arrival. For these patients, an average of 9.7 minutes elapsed between the arrival of the BLS and ALS units, respectively. This time interval presents an opportunity for patient deterioration, and yet may also provide a window of therapeutic opportunity for properly equipped and trained BLS providers to administer intranasal naloxone. This data is consistent with a recently published study out of Seattle in which the mean time lapse between the arrival of a BLS provider and a subsequently requested ALS provider for patients suffering from an opioid overdose exceeded sixteen minutes.

The New York SEMAC and New York City REMAC have already approved the use of intranasal naloxone as an acceptable alternative to either intravenous or intramuscular administration. These decisions were supported by published data demonstrating both the efficacy and safety of intranasal naloxone administration. This route also provides the added benefit of reducing the likelihood of unnecessary provider exposures to blood-borne pathogens via inadvertent needlesticks.

The limited skill set necessary for the early administration of naloxone to such patients is further supported by recent efforts to provide opioid-dependent patients with naloxone for use prior to EMS arrival. In 2004, a pilot project by the New York City Department of Health at two syringe exchange programs was conducted. Initial efforts included training 100 intravenous heroin users on overdose prevention as well as the administration of intramuscular naloxone. Between March 2005 and March 2006, the number of participants was increased to an estimated one thousand participants. Since April 2005, a total of 1,485 people have been trained and received naloxone prescriptions. This system reports that approximately 104 lives were saved because of early naloxone administration.

Recognizing the potential benefits, safety, and ease of administration of intranasal naloxone by EMS personnel, we propose a demonstration project to expand the scope of practice of the EMT-B to include the administration of this drug.
Demonstration Project Proposal

Training
From July 1, 2007 through July 31, 2007, all EMT-Bs employed by the FDNY will undergo a standardized training program to include the following:
- signs and symptoms of opioid overdose
- pharmacology of naloxone
- intranasal administration of medications and use of the mucosal atomizer device
- procedure for the use of pre-packaged, intranasal naloxone
- documentation (ePCR) requirements
- quality assurance / patient tracking requirements
- demonstration project protocols (i.e. altered mental status, respiratory arrest)

Location
The demonstration project will include all FDNY BLS personnel within the five boroughs of New York City.

Duration
One year beginning August 1, 2007 and ending July 31, 2008.

Logistics
Two 1cc syringes, prefilled with 2mg of naloxone, attached to a mucosal atomization device will be stocked on each BLS ambulance and other FDNY vehicles commonly staffed with BLS personnel (i.e. MERVs, MRTU, LSU, gators, supervisory vehicles). Additional stock will be made available at battalion depot locations for resupply purposes.

Inclusion Criteria
Naloxone will be administered by the EMT-B, as per protocols (attached), in the following patients:
- patients age >13
- absence of on-scene ALS providers
- alteration of consciousness (defined as P or U on the AVPU scale)
- respiratory rate <8

Exclusion Criteria
Naloxone administration by the EMT-B will be contraindicated in the following instances:
- documented allergy to naloxone
- alteration of consciousness or respiratory depression of presumed traumatic etiology
- cardiac arrest
severe epistaxis

Procedure
The EMT-B will be trained to administer intranasal naloxone as follows:
1. Verify that inclusion and exclusion criteria support administration.
2. Remove prefilled syringe and attached mucosal atomizer device from packaging.
3. Insert atomizer until flush with external nare.
4. Depress plunger to ensure delivery of total volume of syringe contents.
5. Remove syringe and atomizer from the patient’s nare.
6. Dispose of syringe and atomizer in approved receptacle.
7. Monitor patient respirations and mental status for signs of improvement and/or deterioration.
8. If no improvement after five minutes and/or deterioration in the patient’s respiratory status is noted, repeat procedure once using other nare.

Documentation
In addition to the requirements outlined in the FDNY’s ePCR manual, the EMT-B will be required to document the following for every case in which intranasal naloxone is administered:
- respiratory rate and AVPU score prior to administration(s)
- number of doses delivered
- shield number for EMT-B administering the medication
- time of drug administration(s)
- respiratory rate and AVPU score after administration(s)
- adverse effects / events (e.g. epistaxis, emesis, seizures)

Quality Assurance
Every use of intranasal naloxone by EMT-Bs will be reviewed within 48 hours by the physicians of the FDNY Office of Medical Affairs. In addition to the above documentation requirements for the prehospital medical record, every use of intranasal naloxone will also require that the EMT-B complete an on-line quality assurance survey. The information from this survey will be automatically emailed to the Office of Medical Affairs and combined with information from the ePCR and computer-aided dispatch data. Compliance with this quality assurance mechanism will be ensured by linking its completion with the restocking procedure, preventing the EMT-B from receiving from their EMS Station supervisor any resupply rations without verification that the quality assurance measures have been completed.

The information from the above sources, as well as optional interviews with the EMT-Bs, will be combined to ensure that the following data points are collected for every patient:
- date
- CAD number
- EMS Station number
- EMS unit number
- Shield number of EMT-B who administered medication
- Patient name
- Patient age
- Patient sex
- Presenting complaint
- Call-type
- Indication (respiratory versus altered mental status)
- Initial respiratory rate
- Respiratory rate following administration
- AVPU score prior to and following administration
- BLS response time
- ALS response time
- BLS to ALS interval
- Scene time
- Transport time
- Destination hospital
- Use of assisted ventilation
- Occurrence of any of the following (if documented): intubation, cardiac arrest, on-scene death, aspiration, epistaxis, seizures, patient agitation or other signs of narcotic withdrawal, ALS documentation of hypoglycemia
- Total dose delivered
- Comments
- Suspected etiology
- Protocol violations

**Data Reporting / Review**
Weekly and cumulative data reviews will be undertaken by the Office of Medical Affairs. Periodic reports will be given to both the New York SEMAC and New York City REMAC. A final report will be made available to both bodies prior to January 1, 2009 for consideration of more widespread implementation.