Prehospital Fentanyl Field Trial Proposal

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City of Berkeley Fire Department
Alameda County Emergency Medical Services

1. Description of the procedure or medication requested.

Please see enclosure 1

2. Description of the medical conditions for which the procedure/medication will be utilized.

Fentanyl will be used for the very same indications for which we are currently using morphine sulfate. However, we will continue to carry morphine for ischemic chest pain.

3. Alternatives (Please describe any alternate therapy(ies) considered for the same conditions and any advantages and disadvantages.

Please see enclosure 2

4. An estimate of frequency of utilization:

During 2006 the City of Berkeley Fire Department Paramedics provided pain management to 300 patients using Morphine. It is estimated that the paramedics at Berkeley Fire will provide pain management using Fentanyl to 300+ patients during the course of the 1year trial study.

5. Other factors or exceptional circumstances.

Please see enclosure 3

6. Any Supporting Data, including relative studies and medical literature.

Please see enclosure 4

7. Recommended policies/procedures

Please see enclosure 5

8. Description of the training and competency testing required to implement the medication.

Please see enclosures 6 and 7

9. Copy of the local EMS System Evaluation and Quality Improvement Program plan for this request.

Please see enclosures 8 and 9

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Enclosure 1

Description of Medication

Fentanyl Citrate Injection, USP

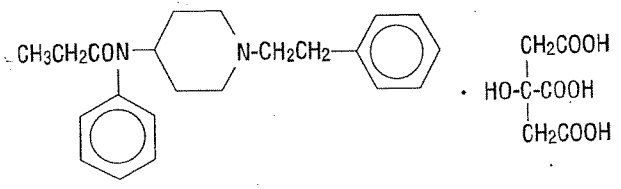
CII

R_x only

DESCRIPTION

Fentanyl Citrate Injection is a sterile, non-pyrogenic solution for intravenous or intramuscular use as a potent narcotic analgesic. Each mL contains fentanyl citrate equivalent to 50 mcg (0.05 mg) fentanyl base in Water for Injection. pH 4.0–7.5; sodium hydroxide and/or hydrochloric acid added, if needed, for pH adjustment. Contains no preservative.

Fentanyl citrate is chemically identified as *N*-(1-Phenethyl-4-piperidyl)propionanilide citrate (1:1) with the following structural formula:



$C_{22}H_{28}N_2O \cdot C_6H_8O_7$ MW 528.59

CLINICAL PHARMACOLOGY

Fentanyl citrate is a narcotic analgesic. A dose of 100 mcg (0.1 mg) (2 mL) is approximately equivalent in analgesic activity to 10 mg of morphine or 75 mg of meperidine. The principal actions of therapeutic value are analgesia and sedation. Alterations in respiratory rate and alveolar ventilation, associated with narcotic analgesics, may last longer than the analgesic effect. As the dose of narcotic is increased, the decrease in pulmonary exchange becomes greater. Large doses may produce apnea. Fentanyl appears to have less emetic activity than either morphine or meperidine. Histamine assays and skin wheal testing in man indicate that clinically significant histamine release rarely occurs with fentanyl. Recent assays in man show no clinically significant histamine release in dosages up to 50 mcg/kg (0.05 mg/kg) (1 mL/kg). Fentanyl preserves cardiac stability and blunts stress-related hormonal changes at higher doses.

The pharmacokinetics of fentanyl can be described as a three-compartment model, with a distribution time of 1.7 minutes, redistribution of 13 minutes and a terminal elimination half-life of 219 minutes. The volume of distribution for fentanyl is 4 L/kg.

Fentanyl plasma protein binding capacity increases with increasing ionization of the drug. Alterations in pH may affect its distribution between plasma and the central nervous system. It accumulates in skeletal muscle and fat and is released slowly into the blood. Fentanyl, which is primarily transformed in the liver, demonstrates a high first pass clearance and releases approximately 75% of an intravenous dose in urine, mostly as metabolites with less than 10% representing the unchanged drug. Approximately 9% of the dose is recovered in the feces, primarily as metabolites.

The onset of action of fentanyl is almost immediate when the drug is given intravenously; however, the maximal analgesic and respiratory depressant effect may not be noted for several minutes. The usual duration of action of the analgesic effect is 30 to 60 minutes after a single intravenous dose of up to 100 mcg (0.1 mg) (2 mL). Following intramuscular administration, the onset of action is from seven to eight minutes, and the duration of action is one to two hours. As with longer acting narcotic analgesics, the duration of the respiratory depressant effect of fentanyl may be longer than the analgesic effect. The following observations have been reported concerning altered respiratory response to CO_2 stimulation following administration of fentanyl citrate to man:

1. DIMINISHED SENSITIVITY TO CO_2 STIMULATION MAY PERSIST LONGER THAN DEPRESSION OF RESPIRATORY RATE. (Altered sensitivity to CO_2 stimulation has been demonstrated for up to four hours following a single dose of 600 mcg [0.6 mg] [12 mL] fentanyl to healthy volunteers.) Fentanyl frequently slows the respiratory rate, duration and degree of respiratory depression being dose related.
2. The peak respiratory depressant effect of a single intravenous dose of fentanyl citrate is noted 5 to 15 minutes following injection. See also **WARNINGS** and **PRECAUTIONS** concerning respiratory depression.

INDICATIONS AND USAGE

Fentanyl Citrate Injection is indicated:

- for analgesic action of short duration during the anesthetic periods, premedication, induction and maintenance, and in the immediate postoperative period (recovery room) as the need arises.
- for use as a narcotic analgesic supplement in general or regional anesthesia.
- for administration with a neuroleptic such as droperidol injection as an anesthetic premedication, for the induction of anesthesia and as an adjunct in the maintenance of general and regional anesthesia.
- for use as an anesthetic agent with oxygen in selected high risk patients, such as those undergoing open heart surgery or certain complicated neurological or orthopedic procedures.

CONTRAINDICATIONS

Fentanyl Citrate Injection is contraindicated in patients with known intolerance to the drug.

WARNINGS

FENTANYL CITRATE SHOULD BE ADMINISTERED ONLY BY PERSONS SPECIFICALLY TRAINED IN THE USE OF INTRAVENOUS ANESTHETICS AND MANAGEMENT OF THE RESPIRATORY EFFECTS OF POTENT OPIOIDS.

AN OPIOID ANTAGONIST, RESUSCITATIVE AND INTUBATION EQUIPMENT AND OXYGEN SHOULD BE READILY AVAILABLE.

See also discussion of narcotic antagonists in **PRECAUTIONS** and **OVERDOSAGE.**

If fentanyl is administered with a tranquilizer such as droperidol, the user should become familiar with the special properties of each drug, particularly the widely differing

durations of action. In addition, when such a combination is used, fluids and other countermeasures to manage hypotension should be available.

As with other potent narcotics, the respiratory depressant effect of fentanyl may persist longer than the measured analgesic effect. The total dose of all narcotic analgesics administered should be considered by the practitioner before ordering narcotic analgesics during recovery from anesthesia. It is recommended that narcotics, when required, should be used in reduced doses initially, as low as 1/4 to 1/3 those usually recommended.

Fentanyl may cause muscle rigidity, particularly involving the muscles of respiration. In addition, skeletal muscle movements of various groups in the extremities, neck and external eye have been reported during induction of anesthesia with fentanyl; these reported movements have, on rare occasions, been strong enough to pose patient management problems. This effect is related to the dose and speed of injection and its incidence can be reduced by: 1) administration of up to 1/4 of the full paralyzing dose of a non-depolarizing neuromuscular blocking agent just prior to administration of fentanyl citrate; 2) administration of a full paralyzing dose of a neuromuscular blocking agent following loss of eyelash reflex when fentanyl is used in anesthetic doses titrated by slow intravenous infusion; or, 3) simultaneous administration of fentanyl citrate and a full paralyzing dose of neuromuscular blocking agent when fentanyl citrate is used in rapidly administered anesthetic dosages. The neuromuscular blocking agent used should be compatible with the patient's cardiovascular status.

Adequate facilities should be available for postoperative monitoring and ventilation of patients administered anesthetic doses of fentanyl. Where moderate or high doses are used (above 10 mcg/kg), there must be adequate facilities for postoperative observation, and ventilation if necessary, of patients who have received fentanyl. It is essential that these facilities be fully equipped to handle all degrees of respiratory depression.

Fentanyl may also produce other signs and symptoms characteristic of narcotic analgesics including euphoria, miosis, bradycardia and bronchoconstriction.

Severe and unpredictable potentiation by MAO inhibitors has been reported for other narcotic analgesics. Although this has not been reported for fentanyl, there are insufficient data to establish that this does not occur with fentanyl. Therefore, when fentanyl is administered to patients who have received MAO inhibitors within 14 days, appropriate monitoring and ready availability of vasodilators and beta-blockers for the treatment of hypertension is indicated.

Head Injuries and Increased Intracranial Pressure

Fentanyl should be used with caution in patients who may be particularly susceptible to respiratory depression, such as comatose patients who may have a head injury or brain tumor. In addition, fentanyl may obscure the clinical course of patients with head injury.

PRECAUTIONS

General

The initial dose of fentanyl citrate should be appropriately reduced in elderly and debilitated patients. The effect of the initial dose should be considered in determining incremental doses.

Nitrous oxide has been reported to produce cardiovascular depression when given with higher doses of fentanyl.

Certain forms of conduction anesthesia, such as spinal anesthesia and some peridural anesthetics, can alter respiration by blocking intercostal nerves. Through other mechanisms (See **CLINICAL PHARMACOLOGY**) fentanyl can also alter respiration. Therefore, when fentanyl is used to supplement these forms of anesthesia, the anesthetist should be familiar with the physiological alterations involved, and be prepared to manage them in the patients selected for these forms of anesthesia.

When a tranquilizer such as droperidol is used with fentanyl, pulmonary arterial pressure may be decreased. This fact should be considered by those who conduct diagnostic and surgical procedures where interpretation of pulmonary arterial pressure measurements might determine final management of the patient. When high dose or anesthetic dosages of fentanyl are employed, even relatively small dosages of diazepam may cause cardiovascular depression. When fentanyl is used with a tranquilizer such as droperidol, hypotension can occur. If it occurs, the possibility of hypovolemia should also be considered and managed with appropriate parenteral fluid therapy. Repositioning the patient to improve venous return to the heart should be considered when operative conditions permit. Care should be exercised in moving and positioning of patients because of the possibility of orthostatic hypotension. If volume expansion with fluids plus other countermeasures do not correct hypotension, the administration of pressor agents other than epinephrine should be considered. Because of the alpha-adrenergic blocking action of droperidol, epinephrine may paradoxically decrease the blood pressure in patients treated with droperidol.

Elevated blood pressure, with and without pre-existing hypertension, has been reported following administration of fentanyl citrate combined with droperidol. This might be due to unexplained alterations in sympathetic activity following large doses; however, it is also frequently attributed to anesthetic and surgical stimulation during light anesthesia.

When droperidol is used with fentanyl and the EEG is used for postoperative monitoring, it may be found that the EEG pattern returns to normal slowly.

Vital signs should be monitored routinely.

Respiratory depression caused by opioid analgesics can be reversed by opioid antagonists such as naloxone. Because the duration of respiratory depression produced by fentanyl may last longer than the duration of the opioid antagonist action, appropriate surveillance should be maintained. As with all potent opioids, profound analgesia is accompanied by respiratory depression and diminished sensitivity to CO_2 stimulation which may persist into or recur in the postoperative period. Intraoperative hyperventilation may further alter postoperative response to CO_2. Appropriate postoperative monitoring should be employed to ensure that adequate spontaneous breathing is established and maintained in the absence of stimulation prior to discharging the patient from the recovery area.

Impaired Respiration

Fentanyl should be used with caution in patients with chronic obstructive pulmonary disease, patients with decreased respiratory reserve, and others with potentially compromised respiration. In such patients, narcotics may additionally decrease

respiratory drive and increase airway resistance. During anesthesia, this can be managed by assisted or controlled respiration.

Impaired Hepatic or Renal Function

Fentanyl citrate should be administered with caution to patients with liver and kidney dysfunction because of the importance of these organs in the metabolism and excretion of drugs.

Cardiovascular Effects

Fentanyl may produce bradycardia, which may be treated with atropine. Fentanyl should be used with caution in patients with cardiac bradyarrhythmias.

Drug Interactions

Other CNS depressant drugs (e.g., barbiturates, tranquilizers, narcotics and general anesthetics) will have additive or potentiating effects with fentanyl. When patients have received such drugs, the dose of fentanyl required will be less than usual. Following the administration of fentanyl citrate, the dose of other CNS depressant drugs should be reduced.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity or mutagenicity studies have been conducted with fentanyl citrate. Reproduction studies in rats revealed a significant decrease in the pregnancy rate of all experimental groups. This decrease was most pronounced in the high dosed group (1.25 mg/kg—12.5X human dose) in which one of twenty animals became pregnant.

Pregnancy

Teratogenic Effects—Pregnancy Category C.

Fentanyl citrate has been shown to impair fertility and to have an embryocidal effect in rats when given in doses 0.3 times the upper human dose for a period of 12 days. No evidence of teratogenic effects have been observed after administration of fentanyl citrate to rats. There are no adequate and well-controlled studies in pregnant women. Fentanyl should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery

There are insufficient data to support the use of fentanyl in labor and delivery. Therefore, such use is not recommended.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when fentanyl citrate is administered to a nursing woman.

Pediatric Use

The safety and efficacy of fentanyl citrate in pediatric patients under two years of age has not been established.

Rare cases of unexplained clinically significant methemoglobinemia have been reported in premature neonates undergoing emergency anesthesia and surgery which included combined use of fentanyl, pancuronium and atropine. A direct cause and effect relationship between the combined use of these drugs and the reported cases of methemoglobinemia has not been established.

ADVERSE REACTIONS

As with other narcotic analgesics, the most common serious adverse reactions reported to occur with fentanyl are respiratory depression, apnea, rigidity and bradycardia; if these remain untreated, respiratory arrest, circulatory depression or cardiac arrest could occur. Other adverse reactions that have been reported are hypertension, hypotension, dizziness, blurred vision, nausea, emesis, laryngospasm and diaphoresis.

It has been reported that secondary rebound respiratory depression may occasionally occur postoperatively. Patients should be monitored for this possibility and appropriate countermeasures taken as necessary.

When a tranquilizer such as droperidol is used with fentanyl citrate, the following adverse reactions can occur: chills and/or shivering, restlessness and postoperative hallucinatory episodes (sometimes associated with transient periods of mental depression); extrapyramidal symptoms (dystonia, akathisia and oculogyric crisis) have been observed up to 24 hours postoperatively. When they occur, extrapyramidal symptoms can usually be controlled with anti-parkinson agents. Postoperative drowsiness is also frequently reported following the use of droperidol.

DRUG ABUSE AND DEPENDENCE

Fentanyl Citrate Injection is a Schedule II controlled drug substance that can produce drug dependence of the morphine type and, therefore, has the potential for being abused.

OVERDOSAGE

Manifestations

The manifestations of fentanyl overdosage are an extension of its pharmacologic actions (see **CLINICAL PHARMACOLOGY**) as with other opioid analgesics. The intravenous LD_{50} of fentanyl is 3 mg/kg in rats, 1 mg/kg in cats, 14 mg/kg in dogs and 0.03 mg/kg in monkeys.

Treatment

In the presence of hypoventilation or apnea, oxygen should be administered and respiration should be assisted or controlled as indicated. A patent airway must be maintained; an oropharyngeal airway or endotracheal tube might be indicated. If depressed respiration is associated with muscular rigidity, an intravenous neuromuscular blocking agent might be required to facilitate assisted or controlled respiration. The patient should be carefully observed for 24 hours; body warmth and adequate fluid intake should be maintained. If hypotension occurs and is severe or persists, the possibility of hypovolemia should be considered and managed with appropriate parenteral fluid therapy. A specific narcotic antagonist such as naloxone should be available for use as indicated to manage respiratory depression. This does not preclude the use of more immediate countermeasures. The duration of respiratory depression following overdosage of fentanyl may be longer than the duration of narcotic antagonist action. Consult the package insert of the individual narcotic antagonists for details about use.

DOSAGE AND ADMINISTRATION

50 mcg = 0.05 mg = 1 mL

Dosage should be individualized. Some of the factors to be considered in determining the dose are age, body weight, physical status, underlying pathological condition, use of

other drugs, type of anesthesia to be used and the surgical procedure involved. Dosage should be reduced in elderly or debilitated patients (see **PRECAUTIONS**).

Vital signs should be monitored routinely.

I. Premedication

Premedication (to be appropriately modified in the elderly, debilitated and those who have received other depressant drugs)—50 to 100 mcg (0.05 to 0.1 mg) (1 to 2 mL) may be administered intramuscularly 30 to 60 minutes prior to surgery.

II. Adjunct to General Anesthesia

See Dosage Range Charts.

III. Adjunct to Regional Anesthesia

50 to 100 mcg (0.05 to 0.1 mg) (1 to 2 mL) may be administered intramuscularly or slowly intravenously, over one to two minutes, when additional analgesia is required.

IV. Postoperatively (recovery room)

50 to 100 mcg (0.05 to 0.1 mg) (1 to 2 mL) may be administered intramuscularly for the control of pain, tachypnea and emergence delirium. The dose may be repeated in one to two hours as needed.

Usage in Children

For induction and maintenance in children 2 to 12 years of age, a reduced dose as low as 2 to 3 mcg/kg is recommended.

Dosage Range Chart
Total Dosage (expressed as fentanyl base)
Low dose—2 mcg/kg (0.002 mg/kg) (0.04 mL/kg). Fentanyl in small doses is most useful for minor, but painful, surgical procedures. In addition to the analgesia during surgery, fentanyl may also provide some pain relief in the immediate postoperative period.
Moderate dose—2 to 20 mcg/kg (0.002 to 0.02 mg/kg) (0.04 to 0.4 mL/kg). Where surgery becomes more major, a larger dose is required. With this dose, in addition to adequate analgesia, one would expect to see some abolition of the stress response. However, respiratory depression will be such that artificial ventilation during anesthesia is necessary, and careful observation of ventilation postoperatively is essential.
High dose—20 to 50 mcg/kg (0.02 to 0.05 mg/kg) (0.4 to 1 mL/kg). During open heart surgery and certain more complicated neurosurgical and orthopedic procedures where surgery is more prolonged, and in the opinion of the anesthesiologist, the stress response to surgery would be detrimental to the well being of the patient, dosages of 20 to 50 mcg/kg (0.02 to 0.05 mg/kg) (0.4 to 1 mL/kg) of fentanyl with nitrous oxide/oxygen have been shown to attenuate the stress response as defined by increased levels of circulating growth hormone, catecholamine, ADH and prolactin. When dosages in this range have been used during surgery, postoperative ventilation and observation are essential due to extended post-operative respiratory depression. The main objective of this technique would be to produce "stress free" anesthesia.

Dosage Range Chart

Maintenance Dose (expressed as fentanyl base)
Low dose—2 mcg/kg (0.002 mg/kg) (0.04 mL/kg). Additional dosages of fentanyl are infrequently needed in these minor procedures.
Moderate dose—2 to 20 mcg/kg (0.002 to 0.02 mg/kg) (0.04 to 0.4 mL/kg). 25 to 100 mcg (0.025 to 0.1 mg) (0.5 to 2 mL) may be administered intravenously or intramuscularly when movement and/or changes in vital signs indicate surgical stress or lightening of analgesia.
High dose—20 to 50 mcg/kg (0.02 to 0.05 mg/kg) (0.4 to 1 mL/kg). Maintenance dosage (ranging from 25 mcg [0.025 mg] [0.5 mL] to one half the initial loading dose) will be dictated by the changes in vital signs which indicate stress and lightening of analgesia. However, the additional dosage selected must be individualized especially if the anticipated remaining operative time is short.

As a General Anesthetic

When attenuation of the responses to surgical stress is especially important, doses of 50 to 100 mcg/kg (0.05 to 0.1 mg/kg) (1 to 2 mL/kg) may be administered with oxygen and a muscle relaxant. This technique has been reported to provide anesthesia without the use of additional anesthetic agents. In certain cases, doses up to 150 mcg/kg (0.15 mg/kg) (3 mL/kg) may be necessary to produce this anesthetic effect. It has been used for open heart surgery and certain other major surgical procedures in patients for whom protection of the myocardium from excess oxygen demand is particularly indicated, and for certain complicated neurological and orthopedic procedures.

As noted above, it is essential that qualified personnel and adequate facilities be available for the management of respiratory depression.

See **WARNINGS** and **PRECAUTIONS** for use of fentanyl with other CNS depressants, and in patients with altered response.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED

Fentanyl Citrate Injection, USP, equivalent to 50 mcg (0.05 mg) fentanyl base per mL, is available as follows:

2 mL DOSETTE ampuls packaged in 10s (NDC 10019-038-67)
5 mL DOSETTE ampuls packaged in 10s (NDC 10019-033-72)

For Intravenous Use by Hospital Personnel Specifically Trained in the Use of Narcotic Analgesics:

10 mL DOSETTE ampuls packaged in 5s (NDC 10019-034-73)
20 mL DOSETTE ampuls packaged in 5s (NDC 10019-035-74)
30 mL *Single Dose* vials packaged individually (NDC 10019-036-82)
50 mL *Single Dose* vials packaged individually (NDC 10019-037-83)

Storage

PROTECT FROM LIGHT.
Keep covered in carton until time of use. Store at 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature].

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Enclosure 2

Enclosure 2

Alternative therapy considered for the same conditions and its advantages and disadvantages.

The only alternative at this time would be to continue using morphine sulfate. For the past 35 years morphine has been the analgesic of choice for managing pain in the pre-hospital setting. It has proven itself to be an effective drug in treating moderate to severe pain. However, patients typically need to have a clear diagnosis, normal mental status, be hemodynamically stable, and have controllable nausea and vomiting. With no anti-nausea medications in the California State Paramedic scope of practice morphine is not the drug of choice in patients complaining of nausea and vomiting. Morphine is also known to cause respiratory depression, sedation, and hypotension (due to histamine release and preload reduction). Despite its track record, morphine is not the drug of choice in patients with multi-system trauma that are hemodynamically unstable, patients who are hypotensive, and patients experiencing a right sided myocardial infarction. Another issue with morphine is titration. morphine is typically given in 2mg increments every 5 minutes. Several EMS systems including REMSA Nevada and Clark County EMS in Washington State, have seen cases where paramedics have given their patients a loading dose of morphine and after 5 minutes seen no change in the patient's discomfort. Paramedics then proceeded to give the next and subsequent doses of morphine. By the time they arrived at the hospital the patient in some cases became obtunded and were subsequently treated with naloxone. What field providers at REMSA Nevada, Clark County EMS, and here at the Berkeley Fire Department are seeing is an onset of action ranging from 5-10 minutes. In the urban pre-hospital setting where transports range from 5-10 minutes it is realistic to say that even if pain management was initiated prior to transport that the patient may not experience any relief until well after arriving at the emergency department. Reno Emergency Medical Services Authority in Nevada and Clark County EMS in Washington have recently changed their protocols regarding the use of morphine. If the patient is hypersensitive to fentanyl, or, if the patient is being transported over a long distance then morphine was to be given every 15 minutes as opposed to every 5 minutes. Pinellas County Florida has done away with morphine completely. For those agencies with short transport times we are looking at patients with complaints of pain who might not be getting the pain management they need.

Enclosure 3

Enclosure 3

An Overview of Agencies Using Fentanyl And Fentanyl Diversion Risk

Fentanyl is an effective pre-hospital analgesic. In a recent article in the Journal of Emergency Medical Services fentanyl was considered to be "the analgesic of choice for managing pain in the pre-hospital setting." In preparing this proposal, multiple agencies in 27 different states were contacted to find out if fentanyl was being used in the pre-hospital setting. 20 out of 27 states contacted have fentanyl in the scope of practice for paramedics. These states and some of the agencies are:

Alaska: Anchorage Fire Dept.
Washington: Fire District 1, Everett Fire Department, and Clark County EMS
Oregon: Multnomah County, City of Eugene Fire Department, City of Ashland Fire Department.
Arizona: Phoenix Fire Department.
Nevada: Reno Emergency Medical Services Authority (REMSA)
Idaho: City of Boise Fire Department.
Utah: South Davis Metro Fire Department, and Cache County EMS.
Montana: Billings Fire Department and the Idaho EMS Authority.
Wyoming: City of Cheyenne, and Cheyenne County EMS
Colorado: Denver Paramedics, and Prudemark Paramedics.
New Mexico: Albeqerque and the New Mexico EMS Authority
North / South Dakota State EMS Authority
Kansas State EMS Authority
Texas: Austin / Travis County EMS
Illinois State EMS Authority.
Kentucky State EMS Authority.
Tennessee: Nashville EMS
Alabama: Mobile Fire Department.
Florida: Pinellas County EMS.
Pennsylvania State EMS Authority.

Interviews were conducted via telephone or e-mail with both state and local medical directors. They were asked the following questions:

1. How long has your state/agency been using fentanyl?
2. What prompted you to move to using fentanyl?
3. What protocols have you initiated regarding dosing?
4. Have you had any reports of adverse reactions in any patients?
5. Have you had any incident reports of diversion?
6. Do you carry morphine in addition to fentanyl?

The following is a summary of the answers to these questions.

1. **How long has your state/agency been using fentanyl?**

South Davis Metro Fire in Utah, the State of North Dakota, and Billings EMS in Montana, have all been using fentanyl for less than one year. The State of Pennsylvania has been using fentanyl for 5 years. The average duration of inclusion in the scope between the remaining agencies was 3 years. Several states including Georgia, Nebraska, and Oklahoma have evaluated the need for fentanyl and will be implementing it into their field policies within a year. All state agencies interviewed have adopted fentanyl into their the optional scope of practice at the discretion of the local medical director.

2. **What prompted your agency to make the move to fentanyl?**

Every state interviewed stated the reason they went to Fentanyl was because of its rapid onset of action and its ability to provide effective pain management to their patients without affecting hemodynamic status. This allows paramedics to treat a wider range of patients, up to and including critical trauma patients. Another reason is fentanyl is so appealing to pre-hospital providers is that it is easy to titrate. Dr. Ryan from REMSA stated "It's much easier to titrate than Morphine because of its rapid onset. It provides nearly instantaneous relief to patients who are in pain." An informal survey of emergency physicians in Northern Alameda County revealed unanimous support for the use of Fentanyl by paramedics.

3. **What protocols have you initiated regarding dosing?**

All agencies are using fentanyl for pain management in patients with complaints of pain resulting from burns, fractures, dislocations, back pain, abdominal pain, soft tissue injuries, and for complaints of pain from causes such as sickle cell crisis, and breakthrough cancer pain. Fentanyl is indicated for both adult and pediatric patients. Pinellas County EMS Florida is the only agency that is using fentanyl exclusively and utilizes it in their cardiac chest pain protocol. All of these agencies carry Morphine for patients with ischemic chest pain or those patients that are sensitive to fentanyl. The average dose for the adult patient is 1mcg/kg with a minimum dose of 25mcg and a max single dose of 50mcg. This can be repeated every 3 minutes to a max of 150mcg. Dr. Jeff Waida from Washington Fire District 1 recently increased the dosing from 1mcg/kg to 3mcg/kg. Dr. Edward Racht, Austin / Travis County EMS stated that they have increased the maximum amount of Fentanyl to 400mcg. Dr. Karin Rhomig, Pinellas County EMS implemented a 2mcg/kg dosing. However, Pinellas County is the only agency found that is using intranasal fentanyl in the pre-hospital setting and has been doing so for over a year and with great success. They are finding that giving fentanyl IN eliminates the risk of needle sticks and is much safer for paramedics to administer. They also found that the onset of action is close to that of IV fentanyl. In addition, it eliminates the possibility of causing an abscess at the injection sight. It also works well in the pediatric population or in patients with a fear of needles. IN fentanyl is also The Pinellas County EMS IN Fentanyl dose is 50mcg (25mcg per nare).

4. **Have you had any reports of adverse reactions in any patients?**

None of the agencies in this proposal have reported any adverse reactions in patients receiving Fentanyl. There were no reports of chest wall rigidity. There were no reports of patients requiring rescue intervention, and no reports of patients suffering permanent injury or death from the administration of pre-hospital fentanyl. There are no documented cases of fentanyl addiction in patients receiving fentanyl in the prehospital setting. It appears that fentanyl addiction typically occurs

in patients who receive continuous pain management during long-term hospital stays.

5. Have you had any incident reports of diversion?

Out of all the agencies listed in this proposal the only agencies that experienced a diversion of fentanyl were in New Mexico, Pinellas County EMS, and Austin / Travis County EMS. Loren Pena of New Mexico State reports 3 diversions statewide in the 5 years it has been in the scope of practice, 2 of those were traced to one person. Pinellas County reports 1 fentanyl diversion during the first year of inception. Austin / Travis County reports 1 diversion of fentanyl since inception. All three of these agencies attribute the diversion to several factors. These factors include the handling, storage, packaging, and tracking of controlled substances. Controlled substances as a whole were easily accessible and packaged in a way that made tampering easy and difficult to detect. All three of these agencies were carrying fentanyl in vials. In most cases the medication had been extracted and replaced with saline. In the Pinellas County EMS case, a paramedic with a previous substance abuse history stated the medicine he found in stock was expired. According to Pinellas County Medical Director, he apparently forged documents stating this and took the medicine home for his personal use. He was caught after an attempt to locate the medicine for proper disposal was made and the forged documents were found. Since these diversions, all three agencies have begun using ampules as opposed to vials, changed their security procedures to include lock boxes with individual user pin codes, and reconfigured their tracking procedures which has yielded no diversions since. It should also be noted that of the 5 Fentanyl diversions 4 of these included simultaneous diversions of morphine. In one case fentanyl, morphine, and midazolam were stolen. Several other agencies interviewed reported past diversions of morphine. These agencies also attributed these to diversions to lack of a proper controlled substances handling procedures and have since changed their policies and have had no diversions. It should also be noted that these same agencies have been addressing the reasons why controlled substances are being diverted. Agencies are conducting training for new employees and recurrent training for all employees on dealing with work stress reduction, post traumatic stress, and drug addiction. In the case of a controlled substance diversion some agencies reserve the right to conduct mandatory drug testing. Drug testing is also mandatory when it is determined that controlled substances have been stolen and the case is handled by law enforcement. In some areas EMTs and paramedics are required to see an addiction specialist if they have found guilty of using controlled substances.

Surprisingly, most agencies reported no controlled substances diversions. These include large agencies such as the Denver Paramedics which has 14 Paramedic ambulances on duty per day. These larger agencies, located in Pennsylvania, New Mexico, Colorado, Oregon, and Arizona attribute this to the procedures they have in place to prevent diversion. These include the use of digital lock boxes requiring pin code access that can be tracked via computer. It also included reducing the number of people allowed access to controlled substances, regular and more frequent (monthly as opposed to quarterly) ambulance and master supply audits, using glass ampules, and tamper proof carrying cases with numbered locking tags. Several agencies that are hospital based utilize that hospital's Pixus system for restock.

6. Do you carry morphine in addition to fentanyl?

All of the agencies listed in this proposal carry morphine in addition to fentanyl for the exception of Pinellas County EMS. Again, morphine is used for patients sensitive to fentanyl or experiencing ischemic chest pain. All of the agencies have experienced no problems with carrying two analgesics. There have been concerns about carrying two narcotics, one of which, fentanyl, is very potent. It should be noted that most agencies in California and across the nation are operating with two

benzodiazapenes, diazepam and the very potent midazolam. Regarding diversion of morphine over fentanyl several of the medical directors interviewed stated they have no reason to believe that Fentanyl would be diverted any more than morphine, nor have they seen this occur.

Enclosure 4

Date last updated: Wednesday, January 18, 2006 10:25 AM Pacific

07/01/2005 | Print Article | EMail Article to a friend |

Simplifying Prehospital Analgesia

By Bryan Bledsoe

July 2005 JEMS

Why certain medications should or should not be used for pain management in the field

By Bryan Bledsoe, DO, FACEP, EMT-P; Darren Braude, MD, MPH, FACEP, EMT-P; Michael W. Dailey, MD, FACEP, EMT-P; Jeff Myers, DO, NREMT-P; Mike Richards, MD, MPA, FACEP, EMT-P; Keith Wesley, MD, FACEP

The single most frequent reason people summon EMS or present to an emergency department (ED) is pain. As emergency practitioners, one of our primary roles is the assessment and treatment of pain. However, studies have shown that, in general, we do a poor job of treating it — especially in the prehospital setting.1,2,3,4

There are several reasons for this. First, pain is incorrectly assumed by many providers to have no impact on the patient's morbidity and mortality. Second, many EMTs and paramedics fail to assess and quantify pain in the prehospital setting and, therefore, fail to properly treat the pain. Further, many myths are used to justify denying patients analgesic therapy.5 Federal and state regulations pertaining to controlled substances can also be intimidating.

Although providing analgesia is a major part of compassionate and professional EMS delivery, many medical directors have not embraced the importance of prehospital analgesic therapy. Often, a service recognizes the vital importance of prehospital analgesia but is dissuaded from pursuing it because of what seems to be a bewildering number of possible agents.

On the contrary, field analgesia should be a mainstay of prehospital care as a simple and safe protocol with three acceptable agents: fentanyl, morphine and the mixed-gas analgesic nitrous oxide/oxygen.6 Many prehospital analgesic treatment decisions can be managed at the discretion of the EMS provider per comprehensive treatment protocols and standing orders. This model has been shown to decrease the time from EMS arrival to administration of analgesia.7

The case for fentanyl

Fentanyl comes as close as anything currently available to being the perfect analgesic for emergency medicine and EMS.8 Fentanyl (Sublimaze) is a synthetic opioid with excellent analgesic effects that are rapid in onset and relatively short in duration.

Action: The onset of action for fentanyl is immediate when given intravenously. Peak effects occur within three minutes, and the duration of action is about 30 minutes. The IV dosage in adults ranges from 25-100 micrograms, roughly comparable to 2.5-10 mg morphine. Because of its short duration of action, there's less concern of masking undiagnosed conditions. Because of its rapid onset, titration is easier and safer.9

Adverse effects: Fentanyl has a favorable side-effect profile. It causes less sedation and less respiratory depression than morphine or meperidine. It also causes less hypotension because it doesn't cause histamine release or much preload reduction. Additionally, it rarely causes nausea or vomiting.

Fentanyl does have anti-sympathetic (sympatholytic) properties. Thus, in very fragile patients whose hemodynamics are entirely sympathetic dependent (e.g., the patient in advanced shock), hypotension may occur with larger doses. However, it's usually not a problem with lower doses.

Patient population: Due to its lack of hemo-dynamic effects, fentanyl can be used in the treatment of multiple-system trauma patients.10 Fentanyl has also proven effective in the prehospital treatment of pediatric patients with moderate to severe pain. In fact, in one study, no adverse events were recorded during five years of prehospital fentanyl administration to air-transported trauma victims younger than 15 years old.11 Fentanyl can also be effectively used in the cardiac patient and is ideal even for those with nausea or cardiogenic shock.

In summary, fentanyl can be used for virtually all patients and has a rapid onset of action, a short duration of effect and few adverse effects. Thus, if you must pick a single agent for prehospital analgesic therapy, fentanyl should be your choice.

The case for morphine

Morphine has been the mainstay of emergency analgesia for hundreds of years. It's an effective analgesic for moderate to severe pain with a proven safety record.

Action: The IV dose of morphine ranges from 1-10 mg, and the onset of action when given intravenously is less than five minutes, with peak effects seen within 15-20 minutes. The duration of effect is usually three to four hours. Morphine causes some sedation and dilation of the venous system, which decreases cardiac preload.

Adverse effects: Adverse effects associated with morphine include hypotension (due to histamine release and preload reduction), flushing, nausea and vomiting, sedation and respiratory depression. The long duration of action raises concern among many physicians regarding the potential masking of pain and subsequent delay in diagnosis, although recent literature refutes this notion.12

Patient population: Morphine is an excellent drug for the prehospital treatment of moderate to severe pain—as long as the patient has a clear diagnosis, normal mental status, normal hemodynamics and controllable nausea and vomiting. Unfortunately, many patients who present with pain in the prehospital setting have abdominal pain of unclear etiology, multi-system trauma, nausea and vomiting, or hypotension. Caution is also warranted in the patient with possible right-side myocardial infarction, because morphine reduces preload and, thus, cardiac output.

Morphine has also been used historically for treatment of CHF with acute pulmonary edema. However, morphine isn't a particularly effective preload-reducing agent, especially when compared with such agents as nitroglycerin. The desired anxiolysis in such patients is probably more effectively and safely achieved with true anxiolytics, such as midazolam, especially given the low doses of morphine generally used in such patients.

The case for nitrous oxide/oxygen mixtures

A nitrous oxide/oxygen mixture (e.g., Nitronox, Entonox) is an excellent analgesic when used according to current guidelines.13 It was introduced into the prehospital setting in the late 1970s.14 It is safe and comes in an administration system that is considerably less bulky than units from a decade ago.

Action: At high concentrations, nitrous oxide is an anesthetic. At lower concentrations, it's an effective analgesic. When used as an analgesic, a fixed mixture of 50% nitrous oxide and 50% oxygen is used. It's self-administered by the patient for analgesia, and its effects dissipate within minutes of mask removal.

Adverse effects: Nitrous oxide is quite safe but must be used with caution in patients who have gas trapped in a closed space (e.g., pneumothorax, small bowel obstruction) because nitrous oxide tends to collect in closed spaces.

Patient population: Nitrous oxide has proven effective for numerous types of pain encountered in the prehospital setting.15,16 It can be used for chest pain, pain associated with traumatic injury and during painful procedures, such as transcutaneous pacing.17

In the past, EMTs have not had the authority to provide prehospital analgesia. However, EMTs can safely administer nitrous oxide/oxygen to prehospital patients under standing orders and protocols following an initial education session.

The case against meperidine

For decades, meperidine (Demerol) was an important drug in emergency medicine. However, with the advent of newer and more effective medications, meperidine use has declined.

Action: Meperidine is used for the treatment of moderate to severe pain. The typical dose of 25-100 mg IV or IM lasts for one to two hours and can be repeated. Like morphine, meperidine can depress respirations. However, meperidine tends to cause more histamine release than does morphine or fentanyl and, thus, has the tendency to cause more side effects. It also tends to cause more euphoria than some other agents. Drugs that cause more euphoria tend to be more often abused than those that don't.

Adverse effects: In addition to the interaction with monoamine oxidase (MAO) inhibitors (described below), adverse reactions to meperidine include coma, severe respiratory depression, seizures, hyperpyrexia (elevated body temperature) and others.

Although it's not known whether other narcotics are free of the risk of such reactions, virtually all of the reported reactions have occurred with meperidine. Because of this and the fact that there are other available and equally effective opiates, many EDs and EMS agencies have removed meperidine from their formulary.

Patient population: Meperidine is absolutely contraindicated in patients taking MAO inhibitors (e.g., Nardil, Parnate). Therapeutic doses of meperidine have occasionally precipitated unpredictable, severe and occasionally fatal reactions in patients who have received MAO inhibitors within 14 days. The mechanism of these reactions is unclear, and the types of reactions vary but are always severe and often fatal.

The case against nalbuphine & butorphanol

Because of the significantly decreased potential for abuse, nalbuphine has been widely used in prehospital care as an analgesic agent.

Action: Nalbuphine (Nubain) and butorphanol (Stadol) belong to a subclass of opiates that are synthetic compounds with both agonistic and antagonistic properties. That is, they will activate some opiate receptors while blocking others. This reaction is similar to administering the opiate antagonist naloxone while at the same time administering morphine. Both nalbuphine and butorphanol are mixed narcotic agonist-antagonists with minimal hemodynamic and respiratory effects and, thus, a reported decrease in the likelihood of abuse.

The typical dose for nalbuphine is 5-10 mg IM or IV and the typical dose for butorphanol is 2-4 mg IV or IM. The duration of effect of both agents is two to four hours.

Adverse effects: Although initial studies seemed to suggest that nalbuphine was an effective alternative to morphine, more recent studies have shown that prehospital use of nalbuphine may be problematic.18,19 In a British study of prehospital nalbuphine usage, researchers found that it offered poor pain control for a high proportion of patients.20

Prehospital nalbuphine therapy, because of its antagonistic properties, could be responsible for increased opiate requirements in patients once they arrive at the ED.21,22 Prehospital nalbuphine can also interfere with subsequent anesthesia induction and maintenance. Thus, nalbuphine administration in the prehospital setting may not be in the best interest of the patient.

Patient population: These agents may stimulate an acute withdrawal syndrome in patients who are dependent on opiates (e.g., cancer patients) because they block some opiate receptors. This blockage also leads to a ceiling effect on analgesia. Once this ceiling is reached, additional doses of the drug will not provide any added analgesia.

In summary, nalbuphine and butorphanol are similar agents and generally provide poor and unpredictable prehospital analgesia. Because of their propensity to interfere with subsequent analgesic dosing and anaesthetic techniques, they should not be used in prehospital care.

The case against ketorolac

Ketorolac (Toradol) is a parenteral NSAID available for use in the United States. Because ketorolac is non-addictive, it has been used in the prehospital setting.

Action: The typical dose of ketorolac is 30 mg IV or 60 mg IM (with reduced dosage in the elderly). The duration of effect is approximately two to six hours. Unlike opiates, ketorolac is a peripherally acting agent. It has been extensively studied and commonly used for dental pain and renal colic (kidney stones). However, renal colic is often both a peripheral and central event, and causes significant sympathetic arousal that is not attenuated by ketorolac. Thus, an opiate is often added.

Adverse effects: Although some studies show it to be equally effective to opiates in single doses, this cannot always be extrapolated to emergency medicine. Some studies have also suggested that ketorolac may actually decrease intra-ureteral pressure during renal colic. And other studies have shown that it may decrease perfusion during renal colic.23

Although ketorolac does not cause hypotension, nausea, sedation or respiratory depression, it does have numerous side effects, including the tendency to cause gastrointestinal and renal toxicity. It's important to remember that ketorolac is a platelet inhibitor and can worsen bleeding in a trauma situation or during surgery.

Patient population: In addition to dental pain and renal colic, ketorolac is also used for patients with musculoskeletal pain. However, researchers found oral ibuprofen equally effective as ketorolac at a fraction of the cost.24

Thus, although ketorolac may have some advantage in renal colic, it's impractical to carry a high-priced drug that is specific for a particular disease when morphine and fentanyl will work equally well.

Summary

Prehospital analgesia can be safely provided with only three agents: fentanyl, morphine and the mixed-gas nitrous oxide/oxygen. Of these three, fentanyl is by far the best agent for general EMS analgesic therapy by paramedics. However, to initiate prehospital analgesia earlier in the EMS response time frame, EMTs should administer nitrous oxide/oxygen. This protocol can easily be added to the EMT education program or through a continuing education session. All of the other agents discussed have absolutely no role in modern prehospital care.

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1: Prehosp Emerg Care. 2006 Jan-Mar;10(1):1-7.

Safety and effectiveness of fentanyl administration for prehospital pain management.

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OBJECTIVE: To determine the safety and effectiveness of fentanyl administration for prehospital pain management. METHODS: This was a retrospective chart review of patients transported by ambulance during 2002-2003 who were administered fentanyl citrate in an out-of-hospital setting. Pre- and post-pain-management data were abstracted, including vital signs, verbal numeric pain scale scores, medications administered, and recovery interventions. In addition, the emergency department (ED) charts of a subgroup of these patients were reviewed for similar data elements. RESULTS: Of 2,129 patients who received fentanyl for prehospital analgesia, only 12 (0.6%) had a vital sign abnormality that could have been caused by the administration of fentanyl. Only one (0.2%) of the 611 patients who had both field and ED charts reviewed had a vital sign abnormality that necessitated a recovery intervention. There were no admissions to the hospital, nor patient deaths, attributed to fentanyl use. There was a statistically significant improvement in subjective pain scale scores (8.4 to 3.7). Clinically, this correlates with improvement from severe to mild pain. CONCLUSION: This study showed that fentanyl was effective in decreasing pain scores without causing significant hypotension, respiratory depression, hypoxemia, or sedation. Thus, fentanyl citrate can be used safely and effectively for pain management in the out-of-hospital arena.

PMID: 16418084 [PubMed - indexed for MEDLINE]

1: J Emerg Med. 2005 Aug;29(2):179-87.

Fentanyl trauma analgesia use in air medical scene transports.

Thomas SH, **Rago O**, **Harrison T**, **Biddinger PD**, **Wedel SK**.

Boston MedFlight, Boston, Massachusetts, USA.

This study assessed frequency, safety and efficacy of prehospital fentanyl analgesia during 6 months' adult and pediatric helicopter trauma scene transports (213 doses in 177 patients). We reviewed flight records for pain assessment and analgesia provision, effect, and complications. Analgesia was administered to 46/49 (93.9%) intubated patients. In non-intubated patients, pain assessment was documented in 112 of 128 (87.5%), and analgesia was offered, or there was no pain, in 97/128 (75.8%). Of the 67 non-intubated patients to whom analgesia was administered, post-analgesia pain assessment was documented in 62 (92.5%) and pain improved in 53 (79.1% of 67). Post-analgesia blood pressure dropped below 90 torr in 2/177 cases (1.1%, 95% confidence interval [CI] 0.1-4.0%). Post-analgesia S(p)O(2) did not drop below 90% in any patients (95% CI 0-2.3%). In this study, prehospital providers performed well with respect to pain assessment and treatment. Fentanyl was provided frequently, with good effect and minimal cardiorespiratory consequence.

PMID: 16029830 [PubMed - indexed for MEDLINE]

1: JEMS. 2005 Jul;30(7):56-63.

Simplifying prehospital analgesia. Why certain medications should or should not be used for pain management in the field.

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Prehospital analgesia can be safely provided with only three agents: fentanyl, morphine and the mixed-gas nitrous oxide/oxygen. Of these three, fentanyl is by far the best agent for general EMS analgesic therapy by paramedics. However, to initiate prehospital analgesia earlier in the EMS response time frame, EMT's should administer nitrous oxide/oxygen. This protocol can easily be added to the EMT education program or through a continuing education session. All of the other agents discussed have absolutely no role in modern prehospital care.

PMID: 16027666 [PubMed - indexed for MEDLINE]

1: Pediatr Emerg Care. 1998 Oct;14(5):321-3.

Links

Prehospital fentanyl analgesia in air-transported pediatric trauma patients.

DeVellis P, **Thomas SH**, **Wedel SK**, **Stein JP**, **Vinci RJ**.

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OBJECTIVE: To review the 5.5-year safety record of a protocol guiding fentanyl administration to pediatric trauma patients undergoing aeromedical transport. METHODS: Retrospective review of an urban aeromedical program's trauma scene responses from October 1991 to March 1997 identified the study population as all pediatric patients (age <15 years) receiving fentanyl for analgesia during air transport. Patients receiving fentanyl concurrently with other agents, eg, paralytics, were not studied. The air transport team consisted of a flight nurse and flight paramedic who provided protocol-driven patient care with off-line medical control. Study patients' flight records were reviewed to determine vital signs (systolic blood pressure [SBP], heart rate [HR], and oxygen saturation [SAT]) before and after fentanyl administration. Postfentanyl vital signs were reviewed for evidence of hemodynamic or ventilatory compromise. Pre- and postfentanyl vital signs were compared with the paired t test ($P < 0.05$). Flight records were also analyzed for narrative information, eg, naloxone administration and assisted ventilation, indicative of fentanyl side effects. RESULTS: Fentanyl (0.33-5.0 microg/kg) was administered 211 times to 131 patients who had a median age of 6.2 years (0.1-14 years), median Glasgow coma score (GCS) of 9 (3-15), and a mean pediatric trauma score of 8.3+/-2.4. Seventy-nine (60.3%) patients were intubated; these patients received 139 (65.9 %) of the 211 total fentanyl doses. No adverse effects from fentanyl were noted in flight record narratives. The median interval between fentanyl administration and postfentanyl vital sign assessment was 9.5 minutes (1-35 minutes). Median postfentanyl changes in SBP and HR were -4.7 and -2.9%, respectively. No patient became hypotensive after fentanyl administration. In nonintubated patients, mean postfentanyl SAT (99.2+/-1.3%) was not significantly different ($P = 0.70$) from prefentanyl SAT (99.1+/-1.3%), and no patient was noted to have clinically significant SAT decrement after fentanyl. CONCLUSION: Retrospective review of more than five years of prehospital fentanyl administration revealed no untoward events. Although prospective definitive demonstration of fentanyl's field use is pending, it is reasonable to continue

Related Links

- Prehospital and emergency department analgesia for air-transported | [Prehosp Emerg Care. 1998]
- [Pediatric prehospital trauma care. A retrospective comparison of air and ground transportati [Unfallchirurg. 2002]
- Fentanyl trauma analgesia use in air medical scene tran [J Emerg Med. 2005]
- Appropriateness of endotracheal tube size and insertion depth in children undergoing ai [Pediatr Emerg Care. 2000]
- Prehospital rapid sequence intubation for head trauma: conditions for a successful program. [J Trauma. 2006]

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discretionary fentanyl administration to injured pediatric children in pain.

PMID: 9814395 [PubMed - indexed for MEDLINE]

Links

1: Prehosp Emerg Care. 1998 Oct-Dec;2(4):293-6.

Prehospital and emergency department analgesia for air-transported patients with fractures.

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OBJECTIVE: To evaluate prehospital and receiving emergency department (ED) analgesia administration in air-transported patients with isolated fractures. METHODS: The study was a retrospective descriptive analysis of flight and hospital records. Study patients were consecutive adults (not pharmacologically paralyzed) with fractures undergoing scene or interfacility helicopter transport during 1994-1996. The study aeromedical program uses two helicopters staffed by a nurse/paramedic flight crew providing protocol-guided care. The receiving ED was in an urban academic Level I trauma center (annual census 65,000). Primary data collected were timing and amount of prehospital and ED analgesia. Analysis was mainly descriptive, with chi-square and nonparametric methods used to compare patients who did and did not receive intratransport fentanyl. RESULTS: 130 patients with isolated fractures underwent air transport during the study period 1994-1996. Of these, 98 (75.4%) received intratransport fentanyl; 20 of 98 (20.4%) received no analgesia in the receiving ED. Patients who did receive repeat analgesia in the receiving ED (n = 78, 79.6% of those receiving prehospital fentanyl) had a median interval of 42.5 minutes (interquartile range 25-100) between ED arrival and analgesia administration; only 62.8% of these patients received their ED analgesia within 60 minutes of arrival. CONCLUSIONS: Some patients receiving intratransport fentanyl received no ED analgesia, and those who did receive ED analgesia often had administration delays surpassing the clinical half-life of intratransport-administered fentanyl. Further study should investigate whether setting-specific analgesia practice differences reflect true differences in analgesia needs, overmedication by prehospital providers, or undermedication by ED staff.

PMID: 9799017 [PubMed - indexed for MEDLINE]

Enclosure 5

Alameda County Fentanyl Pain Management Protocol

Introduction: The goal of this policy is to provide pain management to patients prior to and during transport as part of their treatment. Fentanyl is a powerful synthetic opiate that is 100 times stronger than morphine and should be used cautiously. **Fentanyl should be administered at 1mcg/kg** with **a minimum dose of 25 mcg and a max single dose of 50 mcg**. It should be given in an amount sufficient to reduce their pain. Virtually all patients complaining of moderate to severe pain, regardless of etiology, may be candidates for pain management.

Precautions: Fentanyl should be given **SLOW** IV push. Rapid IV push of fentanyl has been known to cause chest wall rigidity requiring neuromuscular blockade to facilitate airway and breathing management. Because of its potency higher doses of Naloxone may be needed (2-10mg).

Contraindications:
-Hypovolemia
-Hypotension, BP <90 systolic if giving greater than 50 mcg..
-Head injury
-Hypersensitivity
-Ischemic chest pain

Routine Medical Care, monitor the patient closely.
-**Naloxone**, should be readily available to reverse any respiratory depression that may occur. 2-10mg
-Psychological coaching and BLS measures, including cold packs, repositioning, splinting, elevation and or traction splints should be used to reduce the need for pain medication. **However**, pain management should be initiated early, and prior to moving or manipulating patients in a manner that would increase their discomfort.
-The preferred route of administration is intravenous (IV)
-Document level of pain by using any of the following pain measuring tools and express the result as a fraction (e.g 2/10 or 7/10).

Numeric Pain Scale
Visual Analog Scale (VAS)
Wong / Baker "Faces"

Pain Management Criteria	Base Contact	Treatment
Any patient with a complaint of moderate to severe pain including -Extremity injuries -Burn patients -Crush injury patients -Prolonged extrication -Severe back and spinal pain -Immobilized patients -Abdominal pain	**NO**	**02** **IV NS** or saline lock **fentanyl** 25-50 mcg **SLOW** IV push or IM Repeat q3-5 mins. Max dose of 150 mcg
Critical Trauma Patients with: -Abdominal trauma -Thoracic trauma	**NO** Unless > 50 mcg is needed	**O2** **IV NS** or saline lock **fentanyl** 25-50 mcg **SLOW** IV push or IM Max dose of 50 mcg
Other patients with a complaint of significant pain, including: -Head trauma -Decreased respirations -Altered mental status -Women in labor -B/P less than 90 systolic	**YES**	**Contact base physician**

Alameda County Fentanyl Pain Management Protocol
Pediatric (One Month Through 14 Years of Age)

Introduction: The goal of this policy is to provide pain management to pediatric patients pain management prior to and during transport as part of their treatment. Fentanyl is a powerful synthetic opiate that is 100 times stronger than morphine and should be used cautiously. Fentanyl should be administered in an amount sufficient to reduce their pain. Virtually all patients complaining of moderate to severe pain, regardless of etiology, may be candidates for pain management.

Precautions: Fentanyl should be given **SLOW** IV push. Rapid IV push of fentanyl has been known to cause chest wall rigidity requiring neuromuscular blockade to facilitate airway and breathing management. Because of its potency it may take higher doses of Naloxone to reverse its effects, 2-10mg.

Routine Medical Care, monitor the patient closely.
-**Naloxone**, should be readily available to reverse any respiratory depression that may occur.
-Psychological coaching and BLS measures, including cold packs, repositioning, splinting, elevation and or traction splints should be used to reduce the need for pain medication.
However, pain management should be initiated early, and prior to moving or manipulating patients in a manner that would increase their discomfort.
-The preferred route of administration is intravenous (IV)
-Document level of pain by using any of the following pain measuring tools and express the result as a fraction (e.g 2/10 or 7/10).
Numeric Pain Scale
Wong / Baker "Faces"
Behavioral Tool

Pain Management Criteria	Base Contact	Treatment
Any patient with a complaint of moderate to severe pain including -Extremity injuries -Burn patients -Severe back and spinal pain -Immobilized patients -Abdominal pain	**NO**	**02** **IV NS** or saline lock **fentanyl 1 mcg/kg** **SLOW** IV push or IM **May repeat x1 in 5 min** **Max of 100 micrograms**
Critical Trauma Patients including: -Abdominal trauma -Thoracic trauma -Head trauma	**YES**	
-Decreased respirations **-Altered mental status** **-Patients with pain not covered above** **-B/P outside normal limits (refer to LBRT)**	**YES**	

FENTANYL PEDIATRIC DOSE CHART

5kg = 5 mcg
10kg = 10 mcg
20kg = 20 mcg
30kg = 30 mcg
40kg = 40 mcg
50kg = 50 mcg

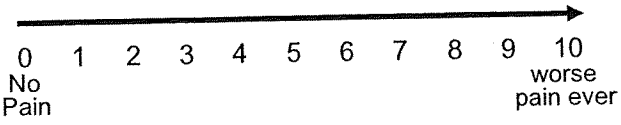
PAIN MANAGEMENT (# 7230)

Introduction: The goal of this policy is to provide *pain management* to patients during treatment and transport. Morphine should be given in an amount sufficient to manage the pain, not necessarily eliminate it. Virtually all patients complaining of moderate/severe pain, regardless of the etiology, may be candidates for pain management, but morphine is a potent analgesic and should not be used indiscriminately.

- **Routine Medical Care** Monitor the patient closely,
- Have **Naloxone** readily available to reverse any respiratory depression that may occur.
- Psychological coaching and BLS measures, including cold packs, repositioning, splinting, elevation and/or traction splints as appropriate, to reduce the need for pain medication.
- The preferred route of administration is intravenous (IV)
- Use the **visual analog scale** to document level of pain prior to and after administration of MS. Express results as a fraction – (e.g.: 2/10 or 7/10)

Pain Management Criteria	Base Contact	Treatment
Any patient with a complaint of significant pain, including: ✓ Significant extremity injuries ✓ Burn patients ✓ Crush injury patients ✓ Prolonged extrication ✓ Severe back and spinal pain ✓ Immobilized patients ✓ Abdominal pain ✓ Total prehospital time ≥ 10 minutes	**No** unless > 15mg MSO_4 is needed	**O2** **IV NS** or **saline lock** **MSO_4**: **IV:** 2-5 mg every 3-5 minutes, titrated to pain, up to 15 mg maximum No IV access: **IM:** 5-10 mg. May repeat in 20 minutes, up to 15 mg maximum
Critical Trauma patients with: ✓ Abdominal trauma ✓ Thoracic trauma	**No** unless > 5mg MSO_4 is needed	**O2** **IV NS** or **saline lock** **MSO_4** **IV** - titrated to pain, up to 5 mg. maximum No IV access: **IM:** up to 5 mg maximum.
Other patients with a complaint of significant pain, including: ✓ Head trauma ✓ Decreased respirations ✓ Altered mental status ✓ Women in labor ✓ B/P < 90 systolic ✓ Total prehospital time < 10 minutes ✓ Patients with pain not covered above	**Yes**	**Contact the base physician prior to administering any pain medication.**

VISUAL ANALOG SCALE



PAIN MANAGEMENT (# 7316)

Introduction: The goal of this policy is to provide pain management to patients during treatment and transport. Morphine should be given in an amount sufficient to manage the pain, not necessarily eliminate it. Virtually all patients complaining of moderate/sever pain, regardless of the etiology, may be candidates for pain management, but morphine is a potent analgesic and should not be used indiscriminately.

- **Routine Medical Care**. Monitor the patient closely,
- **Have Naloxone readily available** to reverse any respiratory depression that may occur.
- **Psychological coaching and BLS measures**, including cold packs, repositioning, splinting, elevation and/or traction splints as appropriate, to reduce the need for pain medication.
- The preferred route of administration is intravenous (IV); however, if an IV cannot be started then give the medication intramuscularly (IM).

Pain Management Criteria	Base Contact Required	Treatment
Any patient with a complaint of significant pain, including: ✓ Significant extremity injuries ✓ Burn patients ✓ Crush injury patients ✓ Severe back and spinal pain ✓ Immobilized patients ✓ Abdominal pain ✓ Patients with total prehospital times > 10 minutes	**No** unless > maximum dose of MSO_4 is needed	**O2** **IVNS** or **saline lock** **MSO_4** (see dose chart below)
✓ **Critical Trauma patients, including:** • Abdominal trauma • Thoracic trauma • Head Trauma ✓ **Decreased respirations** ✓ **Altered mental status** ✓ **Total prehospital time < 10 minutes** ✓ **Patients with pain not covered above** ✓ **B/P outside normal limits -** (see Length Base Resuscitation Tape)	**Yes**	**Contact the base physician** prior to administering any pain medication.

Document level of pain (as a fraction - e.g.: 2/10 or 6/10) prior to and after the administration of MS:

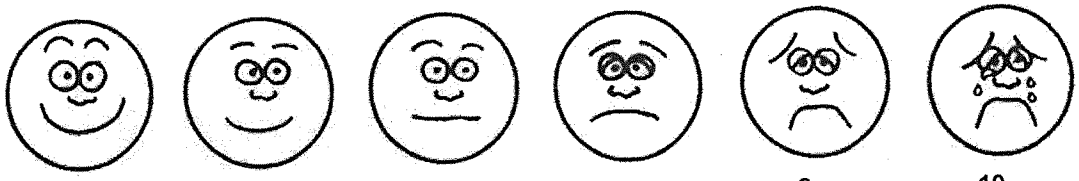
< 3 years old – Behavioral tool or FACES Scale:
3 – 7 years old – FACES scale or visual analog scale
8 – 14 years old – visual analog scale

Pediatric Morphine Dose Chart	
Morphine Sulfate IVP (0.05 mg/kg):	**Morphine Sulfate IM** (0.1 mg/kg):
5kg = 0.25mg 10kg = 0.5mg 20kg = 1.0mg 30kg = 1.5mg 40kg = 2.0mg 50kg = 2.5mg **Maximum single dose: 2.5 mg/dose** **May repeat x1 in 5 minutes**	5kg = 0.5mg 10kg = 1.0mg 20kg = 2.0mg 30kg = 3.0mg 40kg = 4.0mg 50kg = 5.0mg **Maximum single dose: 5.0 mg/dose** **May repeat x1 in 20 minutes**

BEHAVIORAL TOOL

Face	**0** No particular expression or smile	**1** Occasional grimace or Frown, withdrawn, disinterested	**2** Frequent to constant frown Clenched jaw, quivering chin
Legs	**0** Normal or relaxed position	**1** Uneasy, restless, tense	**2** Kicking, or legs drawn up
Activity	**0** Lying quietly, normal position, moves easily	**1** Squirming, tense, shifting Back and forth	**2** Arched, rigid or jerking
Cry	**0** No cry (awake or asleep)	**1** Moans or whimpers; occasional complaint	**2** Cries steadily, screams, sobs, frequent complaints
Consolability	**0** Content, relaxed	**1** Reassured by "talking to, hugging; distractible	**2** Difficult to console or comfort

Wong/Baker FACES Pain Rating Scale



0 No Hurt | **2** Hurts Little Bit | **4** Hurts Little More | **6** Hurts Even More | **8** Hurts Whole Lot | **10** Hurts Worse

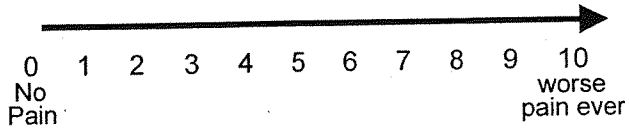
From Wong D.L., Hockenberry-Eaton M., Wilson D., Winkelstein M.L., Schwartz P.: Wong's Essentials of Pediatric Nursing, ed. 6, St. Louis, 2001, p. 1301. Copyrighted by Mosby, Inc. Reprinted by permission.

Brief word instructions: Point to each face using the words to describe the pain intensity. Ask the child to choose face that best describes own pain and record the appropriate number.

Original instructions: Explain to the person that each face is for a person who feels happy because he has no pain (hurt) or sad because he has some or a lot of pain. Ask the person to choose the face that best describes how he/she is feeling.

- **Face 0** is very happy because he doesn't hurt at all.
- **Face 2** hurts just a little bit.
- **Face 4** hurts a little more.
- **Face 6** hurts even more.
- **Face 8** hurts a whole lot.
- **Face 10** hurts as much as you can imagine, although you don't have to be crying to feel this bad.

VISUAL ANALOG SCALE



Enclosure 6

Enclosure 6

Training and Competency Testing

All paramedics at the Berkeley Fire Department will receive a 2 hour in-service training, which will be conducted on duty. The course will consist of the following.

-Pain management in the pre-hospital setting.
-"Myths" of pain assessment
-Review and discuss the various pain assessment tools used in Alameda County as well as other assessment tools.
  Visual Analog Scale
  Numeric Pain Scale
  Wong/Baker "Faces" scale
 -Assessing pain in the elderly patient, in particular, those patients with dementia or any other patient with cognitive dysfunctions.
-Introduction to fentanyl
-Introduction to the Alameda County Fentanyl Pain Management Protocol.
  Indications/Contraindications
  Precautions
  Side effects
  Dosages, including concentration and conversion from micrograms to milligrams.
  Field reporting/Documentation
-Skill Station
  Pain management scenarios in which paramedics will be required to administer the proper dose of fentanyl. This will be done using a syringe with 2cc of normal saline to simulate the 100 micrograms in 2cc of Fentanyl that will be utilized.
  Paramedics will also have to demonstrate the proper routine care to be utilized when administering fentanyl including proper oxygen therapy, pulse oximetry, ECG, and capnography.
-25 post test (Please see enclosure 7)
  Questions will cover fentanyl mechanism of action, dosages, indications, contraindications, side effects, protocol parameters, and routine care.

Enclosure 8

Quality Improvement Program

For quality assurance, 100% of all Patient Care Reports (PCRs) will be scrutinized. Field care audits will be accomplished by the Berkeley Fire Department Quality Assurance Officer on a daily basis.

Each time fentanyl is administered the field paramedic giving the fentanyl will be required to fill out a detailed form. The purpose of the field report is provide data for the agency Quality Assurance Officer. The field report is designed to be easily and quickly completed but provide key information regarding response to therapy and patient outcome. The form is printed on bright paper so that it can be quickly and easily identified.

After the Field Report and PCR are reviewed, the QA Officer will utilize a "Trial Study" form to retrieve even more data. This information will be taken directly from the PCR. The purpose of daily auditing is to identify those calls in which fentanyl was provided. Once all data is collected the QA representative will forward all findings and documentation to the Alameda County EMS Quality Assurance Representative. Both agencies will be reviewing all forms to insure that patient care policies are being adhered to as well as manage and measure the outcome of the use of Fentanyl.

A quarterly meeting to review all findings is recommended; as well as anytime it is deemed necessary by the Medical Director. Medical Control of the use of fentanyl will be maintained the Alameda County Medical and his designated representatives (Base Hospital Physicians). Base Hospital physicians will be briefed that field paramedics will be utilizing fentanyl, given copies of the protocols, and reminded that they may receive base hospital consult for the use of fentanyl. At the end of the trial all data will be reviewed and the following data provided

-Number of patients enrolled
-Number of adults vs. pediatric patients
-Percentage of each pain assessment scale used
-Mean onset of action
-Mean pre-intervention pain score
-Mean post-intervention pain score.
-Mean pre-intervention systolic blood pressure
-Mean post-intervention systolic blood pressure
-Mean pre-intervention SpO2 / Quantity of O2 provided
-Mean post-intervention SpO2 / Quantity of O2 provided
-Adverse reactions

City of Berkeley Fire Dept.
Fentanyl Field Report

Date: _____

Incident Number: _____

Patient Age: _____

Unit # _____

Paramedic administering controlled substance:_____

Pain rating before pain management

NPS VAS WBS

Pain rating after 1st dose of Fentanyl

Dose of fentanyl provided:_____

NPS VAS WBS

Time when there was a change in pain noted after 1st dose given:

<1 minute 1 - 2 minutes 2 - 3 minutes >3 minutes

Pain rating after 2nd dose of Fentanyl

Dose of fentanyl provided:_____

NPS VAS WBS

Time when there was a change in pain noted after 2nd dose given:

<1 minute 1-2 minutes 2 - 3 minutes >3 minutes

Comments:

City of Berkeley Fire Dept.
Fentanyl Pain Management Study

Patient #

Date
Incident number
Patient Age

Chief Complaint

Mechanism of injury / Nature of illness

Pre-analgesia pain score:

Pre-analgesia pain scale used:

Pre-analgesia vital signs:

Respirations
Pulse
Blood Pressure
Spo2
EtCO2

1st Dose of fentanyl

Dose

Time given

Revised pain score after
<1 minute
1 minute
2 minutes
3 minutes

Pain scale used:

Post analgesia vital signs:
Respirations
Pulse
Blood Pressure
SpO2
EtCO2

2nd Dose of fentanyl

Dose
Time given
Revised pain score after

<1minute
1 minute
2 minutes
3 minutes

Pain scale used:

Post analgesia vital signs:
Respirations
Pulse
Blood pressure
SpO2
EtCO2

High pain score
Low pain score
Mean Pain score

High Systolic BP
Low Systolic BP
Mean Systolic BP

Enclosure 9

City of Berkeley Fire Department Controlled Substance Procedures.

The City of Berkeley Fire Department will present its controlled substance procedures during the presentation of this proposal. The City of Berkeley Fire Department operates 3 ALS, dual paramedic ambulances with BLS Engines. The City of Berkeley, in response to recent events in California regarding controlled substance diversion, has conducted an internal audit of its system. Although the Berkeley Fire Department has had zero diversions, the following conclusions were made:

-Limit the number of people who have access to controlled substances. The BFD has 136 sworn personnel. The policy will limit access to controlled substances to the 36 paramedics assigned to the ambulances, the 3 paramedic supervisors, and the EMS division chief and captain.
-Limit the number of people with access to the controlled substance master supply safe to the three paramedic supervisors, the on duty Assistant Chief, and the EMS Division Chief and Captain.
-Utilize a digitally locked safe for mater supply storage that requires two personal pin codes to gain entry and logs who made entry into the master supply safe.
-Utilize a digitally locked box in the ambulances that can only be opened by pin codes assigned to each paramedic. A pin number will be chosen by each paramedic and will be their personal code. Each time the box is opened a log entry is made which can then be retrieved by a paramedic supervisor for auditing or investigation purposes.
-Utilize an ampule by ampule tracking system. Each ampule or preload syringe will be assigned a tracking number which will allow management staff to know the location of each and every medication and track its use.
-Color code all master supply forms to reflect different controlled substances and provide controlled substance usage forms that match those master supply forms for ease of tracking.
-Conduct monthly audits and unscheduled audits of all controlled substances.
-Conduct new employee and recurrent training on dealing with stress in the work place, post traumatic stress, drug addiction, and controlled substance procedures.