

# Authorized and Unauthorized (“PCA by Proxy”) Dosing of Analgesic Infusion Pumps: Position Statement with Clinical Practice Recommendations

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## ■ ABSTRACT:

The American Society for Pain Management Nursing (ASPMN), in order to address sentinel alerts issued by JCAHO in 2004 and ISMP in 2005 concerning “PCA by Proxy”, has developed a position statement and clinical practice recommendations on Authorized and Unauthorized (PCA by Proxy) Dosing of Analgesic Infusion Pumps, approved by the Board of Directors in June of 2006. In short, ASPMN does not support the use of “PCA by Proxy”. ASPMN does, however, support the practice of Authorized Agent Controlled Analgesia in a variety of patient care settings when the agency has in place clear guidelines outlining the conditions under which this practice shall be implemented and outlining monitoring procedures that will insure safe use of the therapy. In addition to outlining this position, the paper clarifies and distinguishes between the unsafe practice of “PCA by Proxy”, in which unauthorized individuals activate the dosing button of an analgesic infusion pump for a patient receiving Patient Controlled Analgesia, and the safe practice of Authorized Agent Controlled Analgesia (AACA). Furthermore, the paper examines the ethical and safety issues and outlines the necessary screening and patient/family education needed to implement AACA. The position statement describes criteria for the use of AACA, guidelines for selection and education of the authorized agent, key prescription and monitoring recommendations during therapy, and quality improvement activities to insure

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**safety and effectiveness.**

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Patient Controlled Analgesia (PCA) was first introduced three decades ago. As the understanding of pain and pain management improved, the use of PCA technology continued to advance, moving PCA into the mainstream of patient care. By the 1990s, PCA became a common technique for managing pain, especially in the postoperative period. Not all patients, however, are good candidates for PCA therapy. For example, young children are not developmentally able to self dose with an analgesic infusion device. Studies done in the early 1990s to determine the safety of "PCA" in children, therefore, utilized the technique of having nurses and/or family members activate the dosing button of a "PCA pump" in order to deliver analgesics to very young children in a timely and safe fashion (Gureno & Reisinger, 1991; Weldon, et al., 1993). In addition to these studies, which had positive findings, some clinical experts employed and wrote about the not uncommon practice of educated and authorized individuals providing Nurse Activated Dosing or Family Activated Dosing for patients who, for a variety of reasons, could not self administer doses via a pump (Pasero & McCaffery, 1993; Pasero, et al., 1999).

Unfortunately, when many agencies were safely utilizing "PCA pump" technology to expand on the availability of safe, timely analgesic delivery by having such educated nurses and family members activate the analgesic pump, there was also a trend toward extending the use of "PCA" therapy to patients who were less than ideal candidates (Nurse Advise-ERR, 2005a). Due to poor patient selection and/or due to poor PCA prescription, the practice of well-meaning nurses, doctors, and significant others haphazardly pressing the buttons (or advising family and visitors to press the button) evolved, in an attempt to improve pain control. While well intentioned, this practice can lead to serious deleterious effects, including death.

In order to alert the health care community to this potentially lethal practice, the Institute for Safe Medical Practices (ISMP) and the Joint Commission on the Accreditation of Health Care Organizations (JCAHO) issued alerts advising against the practice of "PCA by Proxy" (JCAHO, 2004; Nurse Advise-ERR, 2005a; 2005b). In December of 2004, JCAHO published in its Sentinel Event Alert, "Patient controlled analgesia (PCA) is an effective and efficient method of controlling pain, and when it is used as prescribed and intended, the risk of oversedation is significantly re-

duced. However, serious adverse events can result when family members, caregivers, or clinicians who are not authorized become involved in administering the analgesia for the patient 'by proxy'. [This alert does not address situations in which others are authorized to administer analgesia]" (JCAHO, 2004).

In an effort to comply with JCAHO's recommendations, many health care agencies responded by limiting the technology and advantages that the PCA modality offers to Patient Controlled Analgesia only. The practice of identifying authorized agents to activate the dosing button, Authorized Agent Controlled Analgesia (AACA), was effectively eliminated, which, as JCAHO indicated, had not been an intent of the alert. The loss of a viable method of providing analgesia, especially one which can, at times, offer advantages over other methods of relieving pain was seen as a great loss by the American Society for Pain Management Nursing. Therefore, in 2005 a task force was convened to consider this issue and to provide recommendations concerning the practice of Authorized Agent Controlled Analgesia.

## POSITION STATEMENT

The American Society for Pain Management Nursing (ASPMN) recognizes the need for prompt, safe, and effective pain relief for all and supports the use of Authorized Agent Controlled Analgesia (AACA) for the patient who is unable to self administer analgesics using an analgesic infusion pump. The ASPMN does not support the use of "PCA by Proxy" in which an **unauthorized** person activates the dosing mechanism of an analgesic infusion pump and delivers analgesic medication to the patient, thereby increasing the risk for potential patient harm. ASPMN further delineates that support for AACA is contingent upon a health care agency having in place clear guidelines outlining the conditions under which such practice may be implemented, including monitoring procedures that will insure safe use of the therapy.

## Ethical Tenets

The ethical principles of beneficence (the duty to benefit another) and nonmaleficence (the duty to do no harm) oblige health care professionals to provide pain management and comfort to all patients, including those individuals who are vulnerable to the undertreatment of pain, are unable to speak for themselves, and lack the ability to self administer medications. In situations where a person is unable to self administer analgesics due to cognitive or physical limitations, a consistent care provider can be educated to assist or to administer analgesics.

Providing quality and comparable pain management to individuals who cannot self administer analgesics is directed by the principle of justice (the equal or comparative treatment of individuals). Respect for human dignity, the first principle in the “Code of Ethics for Nurses” (ANA, 2001), directs nurses to provide and advocate for humane and appropriate care whether that care is for restoration of health, alleviation of suffering or supportive care at the end of life. When analgesics are administered to alleviate suffering and to provide comfort at the end of life, the principle of “double effect” may occur. Double effect occurs when treatment may have the effect of both relieving suffering and hastening death (double effect). If an action, such as AACA, were to cause death at the end of life, provided the primary intention is to relieve pain and not to cause death, then, although the possibility of death can be foreseen, the action is ethically and legally correct and the authorized agent may feel comfortable. Most importantly, there must be a sense of proportionality between the pain and suffering and the action (Liebert, 1998).

Patient safety and patient rights are considered in the third principle of the “Code of Ethics for Nurses” (ANA, 2001). The development of practice standards, policies, and guidelines that promote safety emphasize this principle as well as the principle of nonmaleficence. Based on the principle of justice, this care is given with compassion and unrestricted by consideration of personal attributes, economic status, or the nature of the health problem.

## Definitions

**Patient Controlled Analgesia (PCA)** is a method of pain control designed to allow **the patient** to administer preset doses of an analgesic, on demand (APS, 2003). Although the medications may be delivered via any route, for the purpose of this position statement, the term refers to medications which are administered using an analgesic infusion pump.

**Analgesic infusion pump** (often referred to as **PCA pump**) is an electronic microprocessing machine that can be programmed to deliver a prescribed amount of medication on demand, at specified intervals, by activation (pressing) of a button. It also has the programming options to deliver patient boluses along with a continuous infusion, or a continuous infusion without patient boluses (thus contradicting the term “PCA” pump.) It can also be used to deliver supplemental clinician “boluses” or “loading” doses of medication.

**PCA by Proxy** is a term that describes activation of the analgesic infusion pump by **anyone other than the patient**. The term denotes a variety of prac-

tices and has been used to describe both authorized (approved) and **unauthorized** activation of the device. In this position statement, the term describes **unauthorized** activation of the pump, which the prescriber intended for **patient** controlled analgesia.

**Authorized Agent Controlled Analgesia (AACA)** is a method of pain control in which a consistently available and competent individual is authorized by a prescriber and properly educated to activate the dosing button of an analgesic infusion pump when a patient is unable, in response to that patient’s pain.

**Nurse Controlled Analgesia (NCA)**: the authorized agent is the nurse responsible for the patient.

**Caregiver Controlled Analgesia (CCA)**: the authorized agent is a nonprofessional individual (e.g., parent, significant other).

## Background

### PCA

PCA, which was first introduced in the 1970s (Forest, et al., 1970; Sechzer, 1971), is a method of pain control designed to allow a patient to self administer a dose of an analgesic, usually an opioid, within a prescribed time interval. The patient is able to self administer these analgesic doses by activating the pump’s dosing button. This method of analgesia allows the patient to find an acceptable balance between analgesia and side effects. PCA also affords patients the ability to treat pain safely in a timely and individualized manner.

PCA is considered a common pain management technique in today’s healthcare arena. In many hospitals it is a common modality for postoperative pain management (Ballantyne & Ryder, 2002). It has proven to be both safe and efficacious in adults, adolescents, and children (Allagretta, 2005; Anghelescu, et al., 2005; Macintyre, 2001) when candidates are chosen appropriately. Many studies have also shown a patient preference for this method of analgesia over traditional intermittent injections (Macintyre, 2001).

A fundamental safeguard of PCA is the fact that excessively sedated patients are usually too sedated to activate the dosing button, thereby preventing delivery of further opioid and subsequent clinically significant opioid-induced respiratory depression (Ballantyne, et al., 2002; Pasero & McCaffery, 2005). This safety feature, coupled with careful patient selection, promotes patient safety. Candidates for PCA should be evaluated for cognitive and physical ability to activate the dosing button. The patient must understand the relationships between pain, pressing (activating) the analgesic infusion pump dosing button, and the goal of pain relief (Pasero & McCaffery, 2005). Therefore,

patients who are confused or have other cognitive limitations are not appropriate candidates for PCA therapy. Generally, children less than five years old do not have the developmental capacity to understand the relationship between pressing the dosing button and achieving pain relief (APS, 2003). However, children as young as five years old may successfully use PCA (Yaster & Krane, 1997).

### **PCA by Proxy versus AACA: Clarifying the Issue**

The term PCA by Proxy has been used to describe both unsafe and safe pain management practices. It has been used to describe the unsafe practice whereby an unauthorized person activates the analgesic dosing button for a patient who is receiving patient controlled analgesia (PCA). The term has also been used to describe AACA, which is considered a safe and effective therapy. It is, therefore, necessary to clearly differentiate between these unsafe and safe practices.

One method to assist in this clarification is to use terminology that more accurately reflects the desired practice. See the terms, under definition section, Authorized Agent Controlled Analgesia (AACA), Nurse Controlled Analgesia (NCA), and Caregiver Controlled Analgesia (CCA). Other terms that clearly define an individual who has been identified as the person responsible for activating the dosing button include Designated Agent and Identified Agent.

For the purposes of this paper, the terms Authorized Agent Controlled Analgesia (AACA), Nurse Controlled Analgesia (NCA), Caregiver Controlled Analgesia (CCA), and Authorized Agent will be used.

### **Authorized Agent Controlled Analgesia**

Use of authorized agents to activate the dosing button of an analgesic infusion pump has been described since the early 1990s (Pasero & McCaffery, 1993). According to Pasero, Portenoy, and McCaffery, when discussing designated agent dosing “. . . ways have been found to use PCA technology safely and effectively, such as family-controlled analgesia and nurse activated dosing” (Pasero, et al., 1999). In addition, two studies, published in 1991 and 1993, demonstrated the efficacy and safety of Nurse Controlled and Family Controlled Analgesia (Gureno & Reisinger, 1991; Weldon, et al., 1993).

In 2005, a voluntary, unpublished survey of the American Pain Society Nurses Special Interest Group (SIG) yielded the following results: 16 of 34 (47%) respondents reported that their hospital policies allowed nurse activated dosing of analgesic infusion pumps in specific situations, and nine of 34 respondents (26%) allowed some form of caregiver activated dosing.

Expert practice and recent studies indicate that, under certain circumstances in which the patient and the authorized agent are carefully chosen and educated, AACA is a safe and effective means of providing analgesia to patients who are unable to provide it for themselves (Angelescu, 2005; Berde & Solodiuk, 2003; Lehr & BeVier, 2003; Monitto, et al., 2000; Pasero & McCaffery, 2005; Petterson, et al., 2000; Taylor, et al., 2003). The Society of Critical Care Medicine and the American Society of Health-System Pharmacists report that analgesic infusion (PCA) pumps can be used appropriately for nurse controlled analgesia (NCA) (Jacobi, et al., 2002).

AACA is not a new concept. Nursing has a long history of providing medications to patients who cannot medicate themselves (Pasero, et al., 1999). Advances in technology have allowed the use of an analgesic infusion pump to improve upon this traditional practice. Furthermore, the feasibility of AACA, with the nonprofessional caregiver as the authorized agent (CCA), is supported by the fact that families have been successfully taught to provide highly technological care, such as home infusion therapy (Cox & Oakes, 2005), and to provide complicated medical therapies, such as pain management for adults and children (Beyer & Simmons, 2004). One study showed that parents could manage their child's pain in the home if provided with appropriate information and suitable analgesia upon discharge from day surgery (Jonas, 2003).

### **The Danger of Unauthorized Activation of the Dosing Button**

As discussed, an inherent safety feature of PCA is that a patient must be awake to self administer a dose of medication. The sedated or sleeping patient usually does not press the button, consequently avoiding an overdose. However, unauthorized activation of the dosing button during PCA by someone other than the patient (a loved one, friend, or even health care provider) can have significant deleterious effects. Reports in the literature (Pasero & McCaffery, 2005) as well as sentinel event alerts (JCAHO, 2004; Nurse Advise-ERR, 2005a; 2005b) clearly indicate the potential danger of such unauthorized practice. These warnings should not go unheeded. They underscore the need for education and instructions to health professionals and laypersons about the potentially life-threatening risks of unauthorized dosing.

### **Advantages of AACA**

AACA offers numerous advantages over traditional nurse-administered, or other caregiver, intermittent dosing. It reduces the potential for a variety of



medication administration errors and delays in administering analgesia. In addition, it affords a closed system for the infusion of medication, thereby decreasing risk of infection to entry sites (e.g., IV). It also offers the financial benefits of “reducing waste created by partially used opioid doses and supplies such as syringes, and can also save nursing time” (Noah, 2003).

Perhaps the greatest advantage of Authorized Agent dosing via a pump is the proximity of the medication to the patient. This results in ease of dose administration and titration and more prompt management of incident pain. AACA enables a patient to receive timely, effective opioid analgesia without loss of dignity, periods of uncontrolled pain, or the high side-effect burden (e.g., sedation, vomiting) that are more likely when other methods are used.

## RECOMMENDATIONS

Health care agency will:

- Ensure the implementation of procedures developed with input of physicians, nurses, pharmacists, risk man-

**TABLE 1.**  
**Key Safety Points**

- Everyone (patient, professionals, visitors) should know the ground rules
- PCA is a method of analgesia therapy, NOT the analgesic delivery pump
- AACA is not appropriate if the patient is determined to be able to use PCA
- Therapy is either PCA or AACA, but not both
- If method of therapy is to be changed, the medication order should be changed and documented in the patient record
- The medical order should designate:
  - PCA
  - AACA (specifying NCA, CCA, CCA with NCA coverage)
- Avoid UACA (unauthorized agent controlled analgesia), AKA “PCA by Proxy”
- Identify the authorized agent(s) to the patient, family, visitors, and other caregivers
- Identify the therapy to all agency personnel involved with the patient by a visual method (e.g., sign, label, etc.)
- Inform all unauthorized persons that they must not activate the dosing button even in the absence of the authorized agent
- It remains the responsibility of the health care team to continue to assess pain and treatment effectiveness

Key points are derived from the position paper, with emphasis recommended by the *Executive Director for Patient Safety Initiatives at JCAHO* (Personal communication, Richard Croteau, MD, 8/7/06).

agers, and other appropriate personnel. These procedures shall outline the parameters of AACA use including, but not limited to:

- Guidelines promoting safe and effective management of pain, including frequency of sedation and respiratory status checks during therapy. **Note: When providing and advocating for humane and supportive care along the entire health care continuum the prescription and delivery of AACA must be patient specific. Otherwise, some of the normal safeguards utilized in the delivery of both Patient Controlled Analgesia and AACA would only serve to limit appropriate care to patients who are critically and/or terminally ill; who may be unresponsive and/or at end of life. Parameters which would, under normal circumstances, preclude activating the dosing button, such as unresponsiveness or a slow respiratory rate, may require adjustment in certain circumstances. In the hospice setting especially, the doctrine of “double effect” needs to be both considered and discussed with the family and authorized agent(s).**
- The stipulation that AACA will be administered only in settings where staff are already familiar with the use of PCA and other analgesic infusion therapies.
- The limitation of AACA to only patients who, because of cognitive or physical limitations, can not safely self-administer analgesic doses via an analgesic infusion pump.
- The provision of a mechanism to readily communicate to all health care providers caring for the patient that the patient is receiving AACA, such as chart, bed, or analgesic infusion pump/button label or sign.
- The stipulation that nonprofessional caregiver authorized agent(s) shall be an adult(s) who is:
  - consistently with the patient.
  - willing and able to learn to provide AACA.
  - demonstrates the ability to perform the responsibilities as detailed in the Recommendations section labeled “Caregivers will:”
- The need to limit the number of authorized agents to **one at a given time**; alternative authorized agents may be designated to provide respite and/or coverage.
- Provision of a prescribing mechanism specifically designed for AACA, such as a preprinted AACA order set.
- When PCA or AACA is to be administered, provide educational materials for patients and families regarding the principles of PCA and the negative consequences of **unauthorized** activation of the analgesic infusion pump dosing button.
- When AACA is to be administered, provide educational materials for each authorized agent regarding the requirements of being an authorized agent and the policies and procedures that must be followed when AACA is used.
- Provide a means for nurses and other staff members to record:
  - Identity of authorized agent(s)

- Caregiver authorized agent education and feedback.
- Amount of medication given over a specified period of time.
- Assessment and reassessment of effectiveness of therapy.
- Provide ongoing education for all patient-care staff specifically emphasizing
  - The dangers of **unauthorized** caregiver doses.
  - The need to follow the institution's policy and procedure for AACA.
- Assure that use of AACA (especially in the case of CCA) does not preclude appropriate nursing observation, assessment, and management customary for other patients receiving analgesic infusion therapies.
- Provide ongoing evaluation of outcomes regarding AACA (e.g. quality improvement activities, trends in incident reports, adverse events, and medication errors) including, but not limited to:
  - Appropriateness of AACA orders.
  - Documentation of caregiver education.
  - Adverse events related to AACA.
  - Interventions in response to the above

#### Prescribers will:

- Collaborate with the nursing staff regarding the need for AACA considering:
  - The anticipated course of illness and associated pain requiring the need for opioid analgesia.
  - The need for prompt management of incident-related pain (e.g., need for immediate opioids for dressing changes, repositioning in bed, or ambulation).
- Prescribe PCA if and as soon as the patient is able to self-administer analgesia.
- Follow established policy for the care of patients receiving PCA and AACA.

#### Nurses will:

- Follow established policy for the care of patients receiving PCA and AACA.
- Educate patients, family members, and other visitors about the purpose and proper use of analgesic pumps, including pump safety features and the dangers of **unauthorized** activation of the dosing button.
- Participate in the selection of authorized agents by assessing the willingness and abilities of the patient's caregiver or significant other to understand AACA and follow instructions.
- Provide and document that the authorized agent has received, reviewed, and applied verbal and written instructions which include, but are not limited to, the following:
  - How to recognize specific patient behaviors or circumstances that may indicate the need for analgesia.
  - How to activate the analgesic dosing button.
  - How to recognize **patient specific** indicators that would preclude activating the dosing button at a given time (e.g., sedation, shallow or irregular respirations). Such indicators require definition by prescription for each particular patient.

- Appropriate actions to take in the event of pump malfunction, unrelieved pain, excessive side effects, or other such medical emergencies, and any other conditions the health care agency and/or particular prescriber specifies.
- Information that activation of the dosing button should **only** occur if the patient is awake and/or the patient's words or behavior indicate to the authorized agent that the patient is in pain or pain is anticipated (incidental pain), *unless otherwise specified by the prescriber, such as in the case of the unresponsive and/or end of life patient.*
- When **not** to activate the dosing button, such as:
  - For purposes other than pain relief (e.g., not for the purposes of having the patient sleep or to become less anxious).
  - While the patient is sleeping.
  - If the patient cannot be readily awakened to baseline.
  - If the patient is having abnormal breathing, as defined by prescriber (shallow, slow, or noisy).
- How to recognize pain, sedation, and respiratory depression.
- What to do if an emergency situation arises (e.g., stimulate the patient, notify nurse, or call 911 in the home setting). Include emergency numbers as appropriate.
- Continually assess the ability of the caregiver to provide AACA. If the nurse has any concerns regarding a caregiver's ability to administer AACA, the nurse must stop the caregiver from activating any further doses, inform the prescriber of the situation, and obtain an order for an alternative means of pain relief.
- Provide a complete report of the patient's tolerance of AACA, including the authorized agent's performance, when the care of the patient is being transferred to another nurse.
- Communicate to all other health care providers that the patient is receiving AACA (e.g. chart, bed, or analgesic infusion pump/button label or sign).

#### Caregivers will:

- Actively participate in learning the principles of PCA and AACA and verbalize an understanding of the need to provide AACA safely and effectively through:
  - Recognition of the need to activate the dosing button for the responsive patient only when the patient is awake and the patient's words or behaviors indicate the presence of pain and need for analgesia.
  - Recognition of other situations in which the prescriber has authorized the activation of the dosing button for purposes such as incident related pain.
  - In the unresponsive and/or end of life patient, under what circumstances activation of the dosing button should occur.
  - Knowledge of how and when to alert staff if there are any concerns about AACA, including the patient's pain, level of sedation, respiratory status, or any opioid-induced side effects.

- Knowledge that it is necessary to inform other family members and visitors who are **not** designated as authorized agents for the patient, that they **cannot** activate the dosing button even in the absence of the authorized agent.
- Knowledge that only a designated health care provider may educate an authorized agent; that one non-professional caregiver authorized agent may **not** educate another authorized agent.
- Knowledge of when **not** to activate the dosing button, such as if the patient is asleep, does not awaken easily, has a depressed respiratory rate (as defined by prescriber for each individual patient), or for any reason other than pain relief (e.g., sleep or anxiety), *unless otherwise ordered by the prescriber.*
- Agreement not to attempt any reprogramming of the analgesic infusion pump or otherwise violate the infusion system's integrity.

## SUMMARY

A primary goal of the American Society for Pain Management Nursing is to provide prompt, safe, and effective pain management to all individuals with pain. To that end, the organization supports the use of Authorized Agent Controlled Analgesia (AACCA) in a variety of patient care settings where patients are unable to

self-administer analgesia. This position statement describes criteria for the use of AACCA, guidelines for selection and education of the authorized agent, key prescription and monitoring recommendations during therapy, and quality improvement activities to insure safety and effectiveness.

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## SUGGESTED ADDITIONAL READINGS

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