CONSENSUS STATEMENT ON INFECTION CONTROL MEASURES OF SINGLE DOSE VIALS FOR MULTIPLE PATIENTS

By:

(Organizations will be listed in alphabetical order in the final document)

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American Academy of Pain Medicine
American Academy of Physical Medicine & Rehabilitation (PENDING)
American Society of Anesthesiologists (PENDING)
American Society of Interventional Pain Physicians
International Spine Intervention Society
Society of Interventional Radiology (PENDING)
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PROLOGUE

The transmission of bloodborne pathogens during health care procedures continues to occur due to the use of unsafe and improper injection, infusion, and medication administration by health care professionals in various clinical settings in the United States and across the globe. These settings also include interventional pain management practices. Based on a multitude of concerns, the current (April 27, 2001 / revised September 12, 2002) Centers for Disease Control and Prevention (CDC) guidelines state, "Intravenous medication vials labeled for single use, including erythropoietin, should not be punctured more than once. Once a needle has entered a vial labeled for single use, the sterility of the product can no longer be guaranteed" (1). Thus, a single vial of any solution of liquid medication, when initially used, must then be discarded, even if additional medicine is still in the vial. No options are available to draw the remaining medicine into different syringes or to use the medicine within a defined period of time. These recommendations for infection control have been universally applied since January 2010 (2).

However, these regulations are not based on evidence or sound reasoning, but rather are based on limited case-reports, inaccurate and incomplete information, and conjecture. Education and multiple other guidelines relating to a sanitary environment, such as traffic flow, monitoring of air flow exchange, infiltration systems for hospitals and ambulatory surgery centers, regular facility cleaning and disinfection, and routine hand washing are essential and common-sense approaches. However, the guidelines covering safe injection practices with single-dose vials and the requirement to only use each vial for a single patient, is overreaching, expensive, and burdensome to the practice of medicine and may ultimately result in reduced access. This is especially true for closed procedures, including interventional techniques.
Of all the regulations and recommendations controlling the practice of medicine in the United States, infection control practices, including safe injection and medication vial utilization, are among some of the most burdensome and expensive, and are based on inadequate evidence and improper applications.

**EVIDENCE**

The evidence synthesis and subsequent regulations by CDC and the Centers for Medicare and Medicaid Services (CMS) do not follow administrations’ directive on evidence-based medicine and recommendations from Institute of Medicine (3-5).

Numerous case reports and in fact, studies have failed to show a causal relationship to infections (6-22); a well-controlled study (22) illustrated there were no infections in over 18,000 procedures and 12,000 encounters over a period of approximately 1½ years.

Thus there is no evidence to date that single dose vials, when used for multiple patients, are responsible for infections if proper infection control measures are applied. The current reimbursement levels for office practices may essentially be less than the cost of multiple drugs used in the form of single dose vials to perform interventional techniques. These savings for interventional techniques in the United States could be approximately $750 million per year, a conservative estimate, and could even be enormous if all drugs are considered.

**CONSENSUS**

All the signatories to this consensus statement, along with other professionals, strongly support appropriate infection control measures, and strongly oppose inappropriate regulations. There are no dissenting opinions that transmissions of blood borne pathogens during health care procedures continue to occur, but those transmissions are due to unsafe and improper sterile precautions.
CDC RECOMMENDATIONS

The CDC have provided multiple recommendations over the years, citing an article published on May 17, 2001 in the New England Journal of Medicine entitled “Serratia Liquefaciens Bloodstream Infections from Contamination of Epoetin Alfa at a Hemodialysis Center” (23). The CDC documented that at the hemodialysis center involved, overfill doses from single-use vials of epoetin alfa were saved after being used for one or more patients and the residual volume was pooled into one vial, and then given to other patients (1). Because of the CDC regulations, Program Development of the Division of Health Care Quality Promotion was contacted by personnel from a number of dialysis centers to discuss these recommendations. Following this, the CDC recommended to the CMS that if certain procedures are strictly adhered to and enforced, re-entry and re-use of vials of intravenous epoetin alfa, iron, or vitamin D, labeled for single-use, when used within 4 hours, would have a low risk of patient infection.

Dr. Jarvis concluded that the CDC believed if these procedures were strictly followed and enforced, re-entry and re-use of single-vials of injectable medications administered to hemodialysis patients during the specified time periods would have a low risk of patient infection (23).

CMS REGULATION

Following the above recommendation from the CDC (23), CMS issued a memorandum on September 12, 2002 to state survey agency directors and associate regional administrators with 6 recommendations provided by Dr. Jarvis as follows (24):

1. All doses must be drawn-up by a licensed professional whose scope of practice includes administration of parenteral medications and knowledge of aseptic technique.
2. All doses from a given vial should be drawn-up and administered within a 4-hour period.

3. Only one vial of a given concentration of the medication should be opened and used by the administering professional at any given time. A second vial of the same medication must not be opened until the previous vial is discarded.

4. Any opened vials or filled syringes (with epoetin alpha, iron, or vitamin D) must be discarded if not used within 4 hours of first puncture of the vial. Vials must be labeled to document the time of first entry and maintained at a temperature of 2-8 degrees Celsius (or 36-46 degrees Fahrenheit) during non-use.

5. Residual amounts of these medications (either in the vial or syringes) must never be pooled with medication from another vial or syringe. If a patient requires more medication than is in a single, drawn syringe, then medication from a separate vial should be drawn into a separate syringe for administration.

6. Each facility must have in place a process monitoring (quality assurance) program which ensures compliance with these policies and procedures. These policies must include: a) recording data on infections in treated dialysis patients; and b) unannounced practice audits involving quality assurance staff observing performance of re-use techniques.

**OUR CONSENSUS**

Based on the above evidence and the CDC’s flexibility, and considering the expensive nature affecting access to care for these interventions, and considering that patients receiving interventional pain procedures are much healthier than end stage renal disease patients, the following have been accepted.
1. All doses must be drawn-up by licensed professionals whose scope of practice includes administration of parenteral medications and knowledge of aseptic techniques.

2. All doses from a given vial should be drawn-up and administered within a 12-hour period.

3. Only one vial of a given concentration of the medication should be opened and used by the administering professional at any given time. A second vial of the same medication must not be opened until the previous vial is discarded.

4. Any opened vials or filled syringes (contrast medium, local anesthetic, steroids, or other drugs) must be discarded if not used within 12 hours of the vial’s first puncture. Vials must be labeled to document the time of first entry and maintained at a temperature of 2-8 degrees Celsius (or 36-46 degrees Fahrenheit) when not in use.

5. Residual amounts of these medications (either in the vial or syringes) must never be pooled with medication from another vial or syringe. If a patient requires more medication than is in a single, drawn syringe, then medication from a separate vial should be drawn into a separate syringe for administration.

6. Each facility must have in place a process monitoring (quality assurance) program which ensures compliance with these policies and procedures. These policies must include: a) recording data on infections in treated patients; and b) unannounced practice audits involving quality assurance staff observing performance of re-use techniques.
REFERENCES


University Medical Center, and Institute for Health Policy, 2006.


