THE NEGATIVE EFFECTS OF SINGLE DOSE VIAL IMPLEMENTATION

SINGLE DOSE VIAL IMPLEMENTATION

Implementation of Single Dose Vials for Infection Control May Lead to Critical Shortage of Drugs and Impede Access to Patient Care.

The recommendations for infection control which have been universally applied since January 2010, are not based on evidence or sound reasoning, but rather are based on limited case-reports, inaccurate and incomplete information, and conjecture. Education and other guidelines relating to a sanitary environment, such as traffic flow, monitoring of air flow exchanges, 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 use only one vial per patient may be 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.

There is no evidence to date that single-dose vials, when used in 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 (single-drug vials) or to perform interventional techniques. The costs of each patient will be increased by approximately $80 for each procedure accompanied by declining reimbursements. These savings for interventional techniques across the country could be approximately $750 million per year and many times over globally if all drugs are considered, which is a conservative estimate.

REGULATORY BURDEN

Out of the multitude of 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. There are no dissenting opinions that 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, not only in the United States, but also across the globe. These reports also include interventional pain management practices and, consequently many unnecessary guidelines and regulations have been developed and imposed. However, these guidelines are far from being evidence-based and may be based only on a relative risk reduction or other factors.

Improperly reported case reports and improperly performed studies have failed to show causal relationship or even the presence of infections, but well-controlled reports have illustrated that there was no difference at all. In fact, in a study of over 18,000 procedures, 12,000 encounters over a period of approximately 1½ years found no infections at all.

ASIPP’S CONCERNS AND RECOMMENDATIONS

While we are strong supporters of appropriate infection control measures, we oppose inappropriate ones. To implement the full guidelines is extremely expensive and difficult, with increases in not only the monetary expenses, but also personnel and stress, thus reducing the quality of care and access to services and in some cases total elimination. The cost of single-dose vials is enormous, with the procedural cost of contrast medium jumping from $6 to $60 in the face of increasing regulations and decreasing reimbursement. This will increase the drug costs not only for the contrast medium (Omnipaque, etc.), but also for other drugs which may increase the cost 4 to 6 times from past expenditures.

This actually lead to an inability to perform these procedures and
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put may many practices out of business, ultimately eliminating access to services. In some cases it appears that the costs of the drugs alone may exceed the CMS reimbursement. When a lumbar epidural injection is performed in an office setting, Medicare reimburses $151.48; the office overhead portion is $87.83. The costs of the drugs include contrast medium at $60, in addition to local anesthetic, intravenous fluids, steroid, and sedation, bringing the total expense to $90. In addition, there are other facility, personnel, equipment, and supplies essential to use for these procedures. It is clear that end result could feasibly be the complete elimination of these procedures.

Interventional pain management is specifically affected, even with flawed evidence synthesis and flawed assumptions by NICE. The fundamental difficulty with some of the organizations is their inability to understand methodology and confusing various methodologies and lack of consideration of comments from anyone, even though it seems like an open and transparent process.

We believe that the requirement to use singe dose vials should be eliminated. In doing so, it could save health care, for interventional techniques alone, an estimated $750 million per year plus additional savings in implementation costs across the country.

REFERENCES

3. RWIF, GWUMC, and IHP Staff. Health information technology for interventional techniques: are they based on relative risk management or evidence? Pain Physician 2011; 14:425-434.