POSITION STATEMENT:
AMPOULE / VIAL SHARING

Whereas–

SASA has, in 2006, adopted at its Council Meeting the following statement: "SASA to advise members not to share ampoules if hospital charges each patient for a separate ampoule";

Issued in its publication "Pipeline" in 2007"there is not doubt that ampoule sharing is certainly not in our patients' best interest", but recognized that cost concerns may underpin ampoule sharing;

And whereas –

Instances of sharing single ampoulescould lead to patients being at risk, SASA hereby adopts the following policy statement:

Patient interest and best practice

The sharing of ampoules or vials labeled as "single dose" or "single use" to be used for only one patient, **is generally not accepted as good medical or pharmaceutical practice**. These medication are formulated for single-dose use only, which typically means that it does not an antimicrobial agent, and it has not been formulated to ensure that when used on multiple patients, the dosage and strength is exactly as would be required per patient.

Practitioners must in all instances act in the best interest of their patients.

Practitioners are under a legal- and ethical duty to prevent harm. **Sharing single-use vials amounts to off-label use**, and could render the practitioner and facility liable for any harm caused as a result, as the manufacturer instructions were not followed. It could also render the practitioner liable (under common law and/or the Consumer Protection Act) where infections or other negative health implication occur due to such vial sharing.

Certain bodies such as the US Association for Professionals in Infection Control and Epidemiology also recommend that multi-dose vials be dedicated to a single patient. If the single-dose or single-use vial will be entered more than once for a single patient as part of a single procedure, it should be with a new needle and new syringe.

Role of administrators

Administrators of medical facilities, whether in the public- or private sectors must be aware of safe ampoule and injection practices and ensure that all have the knowledge, training, and equipment to safely implement these procedures. They should **refrain from placing practitioners into situations where unsafe practices have to be adopted** in order to render necessary healthcare services.

Pharmacies in private and public facilities should ensure that procurement- and stock management policies and practices support the safety of patients.

Exceptional circumstances

In certain settings healthcare practitioners may believe that **drawing the entire contents of the vial** into a single syringe will not allow for safe and accurate titration of dosage (e.g., pediatric dosing during a surgical procedure). In these circumstances, consideration must be had for the risk of repeated entry into a single-dose or single-use vial for that single patient/procedure.

In cases where there are absolutely no other options (e.g. an emergency and single-vial/single-dose stock is not available), unopened single vial sharingcould take place. This **amounts to compounding** of medicines and pharmaceutical best practice must be followed. Such compounding should be undertaken by professionals that are **trained** in this aspect, which should include matters such as the conditions and practices to prevent harm to patients that could result from microbial contamination, excessive bacterial endotoxins, variability in intended strength, unintended chemical and physical contaminants, and ingredients of inappropriate quality in compounded sterile preparations. Consultation with trained compounding pharmacists is highly recommended.

Challenges

Drug shortages and drug waste concerns must be dealt with appropriately. The existence of these should not be accepted as a justification for adoption unsafe practices.

Medicines shortages, whether as a result of administrative malfunctioning, or supplier shortages, could require compounding of single-use vials to take place. In these instances these shortages could place patients in harm's way. Shortages should be reported immediately to the health facility head and SASA, and, in the public sector, to the National Department of Health's procurement division. Corrective action should be taken to prevent such occurrences in future.

Cost savings can never come at the patient's expense in the form of increased risk, or increased cost to a third party.

Medicines must, in any event by law be sold at the single exist price, viz. the cost per vial must be charged. However, where vials are shared, these cannot be each charged to a patient as if each used a separate vial. Such practice would constitute fraud. It is therefore also from a cost perspective, better to ensure that single vials are used per single patient, as that would not raise any issues under single exit price legislation.

Any unsafe practice carries the risk of increased costs (both healthcare and legal), which may need to be incurred to manage the occurrence of the harm. These risks make ampoule-sharing an unworthy risk to take.

Record-keeping

In order to mitigate possible adverse consequences as a result of vial sharing that took place, it is recommended that practitioners record the circumstances under which such sharing took place, including the steps they had taken to ameliorate any possible risk.

Steps that had been taken previously to address matters such as costs and billing, medicines stock-shortages and/or facility policy in terms of the availability of certain forms of medicine, have to be recorded as well.

Sources

"Ampoule sharing – is it safe and is it best practice?" *Pipeline* 2007 Summer Issue, No 57
HPCSA Ethical Rules, 2006, as amended
The Consumer Protection Act, 2008
http://www.apic.org/Resource_/TinyMceFileManager/Position_Statements/AJIC_Safe_Injection0310.pdf
http://www.cdc.gov/injectionsafety/cdcposition-singleusevial.html
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