Introduction to Hospital Pharmacy

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Outline

- **Minimum standards for pharmacies in hospitals.**

Minimum standards for pharmacies in hospitals.

Elements of Care

- The elements of pharmacy services (*standards*) that are critical to safe, effective, and cost-conscious medication use in a hospital include:

(1) practice management.

(2) medication-use policy development.

(3) optimizing medication therapy.

(4) drug product procurement and inventory management.

(5) preparing, packaging, and labelling medications.

(6) medication delivery.

(7) monitoring medication use.

(8) evaluating the effectiveness of the medication-use system.

(9) research.

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Standard II. Medication-Use

A. Policy Development

- All committees that make decisions concerning medication management and use shall have at least one pharmacist as a member.
- This includes the P&T, infection-control, patient care, medication-use evaluation, medication safety, nutrition, pain management, and information technology committees, as well as the institutional review board (or their equivalents).
- Pharmacists shall be involved in the development, implementation, and assessment of care plans (protocols, critical pathways, disease statement management programs, or clinical practice guidelines), standing orders, and order sets that involve medication therapy.

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B. Formulary Management

B-1 Formulary.

- A well-controlled formulary of approved medications shall be maintained and regularly updated by the P&T committee (or its equivalent).
- The impact of and compliance with the formulary should be periodically reviewed (e.g., through drug-utilization reviews), and the P&T committee should regularly review the formulary for safety information.
- The P&T committee shall be responsible for developing and maintaining written criteria for drug product selection, which shall address formulary requests for medications intended for use in special populations (e.g., pediatric or geriatric populations).
- The P&T committee shall be responsible for developing and maintaining adequate product specifications to aid in the purchase of medications and related supplies.

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B-2. Medication Therapy Monographs.

- Medication therapy monographs for medications under consideration for formulary addition or deletion shall be made available to the P&T committee for use in the decision-making process.
- These monographs should be based on evidence gathered through review and evaluation of the pertinent literature.
- Each monograph shall include a comparative therapeutic, economic, and risk assessment (inclusive of black-box warnings) of each medication.

Heritage Information Systems, Inc.

Drug Monograph

Drug/Drug Class: Voriconazole (Vfend®) / Antifungal

Prepared for: Missouri Medicaid
Prepared by: Heritage Information Systems, Inc.

☒ New Criteria ☐ Revision of Existing Criteria

Purpose

The purpose of this monograph is to provide an extensive review of new therapy to determine whether the reviewed drug should be considered a prior authorization drug or not (open access). While prescription expenditures are increasing at double-digit rates, payors are evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. This review will assist in the achievement o f qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class.

Introduction [1-3]

On May 28, 2002, voriconazole (Vfend®) was approved by the Food and Drug Administration (FDA) for the treatment of deadly fungal infections. Voriconazole is classified as a triazole antifungal agent. Other agents in this class are fluconazole (Diflucan®) and itraconazole (Sporonox®). This medication is indicated for the primary treatment of acute invasive aspergillosis. Additional agents include intravenous amphotericin b and oral and/or intravenous itraconazole therapies. It has also been approved as salvage therapy for rare but serious fungal infections caused by *Scedosporium apiospermum* and *Fusarium spp.* Unlike other agents, voriconazole has been approved in both oral and intravenous (IV) formulations.

Dosage Form(s) [2,3]

Tablets:
- 50mg tablets – white, film– coated, round
- 200mg tablets – white, film–coated, capsule shaped

Powder for Solution for Injection (IV)
- supplied in a single use vial as a sterile lyophilized powder equivalent to 200mg Vfend and 3200mg sulfobutyl ether beta-cyclodextrin sodium (SBECD).

Manufacturer [1-3]

Pfizer, Inc. Distributed by Roerig, Division of Pfizer, New York, New York 10017

Indication(s) [2,3]

Voriconazole (Vfend®) is indicated for use in the treatment of the following fungal infections:
- Treatment of invasive aspergillosis. Treatment of invasive aspergillosis in clinical trials, the majority of isolates recovered were *Asperillus fumigatus*. There was a small number of cases of culture-proven disease due to speicies of *Aspergillus* other than *A. fumigatus*.
- Treatment of serious fungal infections caused by *Scedosporium apiospermum* (asexual form of *Pseudallescheria boydii*) and *Fusarium spp.* including *Fusarium solani*, in patients intolerant of, or refractory to, other therapy.

Clinical Efficacy [2,3]

Mechanism of action/Pharmacology
- Voriconazole (Vfend®) is a triazole antifungal agent. The primary mode of action or voriconazole is the inhibition of fungal cytochrome P-450-medicted 14 alpha-lanosterol demethylation, an essential step in fungal ergosterol biodynthesis. The accumulation of 14 alpha-methyl sterols correlated with the subsequent loss of ergosterol in the fungal cell wall and may be responsible for the antifungal activity of voriconazole. Voriconazole has been shown to be more selective for fungal fungal cytochrome P-450 enzymes than for various mammalian cytochrome P-450 enzyme systems.

Contraindications [2,3]

Vfend® is contraindicated in patients with:
- Known hypersensitivity to voriconazole or its excipients. (There is no information regarding cross-sensitivity between Vfend and other azole antifungal agents.)
- Coadministration of the CYP3A4 substrates, terfenadine, astemizole, cisapride, pimozide, or quinidine can lead to QT prolongation.
- Coadministration with sirolimus – will significantly increase sirolimus concentrations (in healthy subjects).
- Coadministration with rifampin, carbamazepine, and long-acting barbiturates – will significantly decrease plasma voriconazole concentrations.
- Coadministration with rifabutin – significantly increases rifabutin plasma concentrations and rifabutin also significantly decreases voriconazole plasma concentrations.
- Coadministration with ergot alkaloids – may increase the plasma concentration of ergot alkaloids, which may lead to ergotism.

Warnings [2,3]

Visual disturbances
- The effect of Vfend® on visual function is not known if treatment continues beyond 28 days. If treatment continues beyond 28 days, visual function including visual acuity, visual field, and color perception should be monitored.

Hepatic toxicity
- In clinical trials, there have been uncommon causes of serious hepatic reactions during treatment with Vfend® (including clinical hepatitis, cholestasis, and fulminant hepatic failure, including fatalities).
- Liver function tests (LFTs) should be evaluated at the start of and during the course of Vfend® therapy. Patients who develop abnormal liver function tests during therapy should be monitored for the development of more severe hepatic injury. Patient management should include laboratory evaluation of hepatic function (particularly LFTs and bilirubin). Discontinuation of therapy must be considered if clinical signs and symptoms consistent with liver disease develop that may be attributable to Vfend®.

Adverse Effects [2,3]

The most frequently reported adverse events (all causalities) in the Vfend® therapeutic trials were:

- Visual disturbances
- Headache
- Abdominal pain
- Respiratory disorder
- Fever
- Sepsis
- Nausea
- Vomiting
- Rash
- Peripheral edema
- Diarrhea

The treatment-related adverse events that most often led to discontinuation of Vfend® (voriconazole) therapy were:

- Elevated liver tests
- Rash
- Visual disturbances

Lab test abnormalities: The overall incidence of clinically significant transaminase abnormailites in the voriconazole clinical program was 13.4% if patients treated with voriconazole. Increased incidence of liver function test abnormalities may be associated with higher plasma concentrations or doses. The majority of abnormal liver function tests either resolve during treatment without dose adjustment or following dose adjustment, including discontinuation of therapy.

Drug Interactions [2,3]

Precipitant Drug	Object Drug*		Description
Barbiturates, long acting Carbamazepine	Voriconazole	↓	Coadministration may decrease voriconazole plasma concentration caused by CYP450 induction. Coadministration is contraindicated.
Cimetidine	Voriconazole		Cimetidine increased voriconazole C_{max} and AUC by an average of 18% and 23%, respectively. No dosage adjustment is required.
Phenytoin	Voriconazole	↓	Phenytoin may increase the metabolism of voriconazole via CYP450 induction, therefore, decreasing the C_{max} and AUC.
Voriconazole	Phenytoin	↑	Voriconazole may increase the C_{max} and AUC of phenytoin up to 2 times. Monitor for adverse reactions and phenytoin plasma concentrations.
Rifampin Rifabutin	Voriconazole	↓	Voriconazole plasma concentrations are significantly reduced during coadministration. Voriconazole may increase the C_{max} and AUC of rifabutin by an average of 3 and 4 times, respectivlvely. Coadministration is contraindicated.
Voriconazole	Rifabutin	↑	
Protease inhibitors	Voriconazole	↑	Voriconazole may inhibit the metabolism of protease inhibitors. The metabolism of voriconasole may be inhibited by protease inhibitors. Monitor closely for toxicity. Coadministration with indinavir showed no significant effects on voriconazole or indinavir exposure.
Voriconazole	Protease inhibitors	↑	
Nonnucleoside reverse transcriptase inhibitors	Voriconazole	↑↓	Coadministration may induce or inhibit the metabolism of voriconazole. Monitor for toxicity and effectiveness of voriconazole. Voriconazole also may inhibit the metabolism of an NNRTI. Monitor for drug toxicity.
Voriconazole	Nonnucleoside reverse transcriptase inhibitors	↑	
Proton pump inhibitors	Voriconazole	↑	Omeprazole may increase the C_{max} and AUC or voriconazole by an average of 15% and 40%, respectively. No dosage adjustment is voriconazole is recommended. Voriconazole may increase the C_{max} and AUC of omeprazole by an average of 2 and 4 times, respectively. When initiating voriconazole in patients already receiving omeprazole doses of 40mg or greater, reduce the dose of omprazole by 50%. Voriconazole also may inhibit the metabolism of other proton pump inhibitors that are CYP2C19 substrates.
Voriconazole	Proton pump inhibitors	↑	
Voriconazole	Benzodiazepines	↑	Voriconazole may increase the plasma concentrations of benzodiazepines that are metabolized by the CYP3A4 (ie, midazolam, triazolam, alprazolam). Adjust benzodiazepine dose if needed.
Voriconazole	Calcium channel blockers	↑	Voriconazole may inhibit the metabolism of calcium channel blockers that are metabolized by CYP3A4 (ie, felodipine). Adjust calcium channel blocker dose if needed.

Cost Comparison (at commonly used dosages) [4]

Initial / Loading Dose

Drug®	Strength	Cost per Unit *	Route	Dose	Cost per Day*	Cost per Load*#
Vfend® (Voriconazole)	200mg/20mL vial	$ 0.53/mg	Intravenous	6mg/kg every 12 hours for 2 doses	$ 446.26	$446.26
Sporonox® (Itraconazole)	250mg/25mL vial	$ 0.74/mg	Intravenous	200mg twice a day	$295.80	N/A
Sporonox® (Itraconazole)	200mg Capsule	$ 8.16	Oral	200mg twice a day	$ 32.64	N/A
Amphotericin B (generic) *Geneva Brand*	50mg/10mL vial	$ 0.38/mg	Intravenous	1.0 – 1.5 mg/kg/day®	$ 26.60 - $39.90	N/A
Abelcet® (Amphotericin B)	50mg/10mL vial	$ 2.70/mg	Intravenous	5.0 mg/kg/day®	$ 945.00	N/A
Ambisome® (Amphotericin B)	50mg/10mL vial	$ 3.77/mg	Intravenous	3.0 – 5.0 mg/kg/day®	$ 791.70 – $969.50	N/A
Amphotec (Amphotericin B)	50mg/10mL vial	$ 1.87/mg	Intravenous	3.0 – 4.0 mg/kg/day®	$ 392.70 – 523.60	N/A

* Priced at Average wholesale price (AWP) utilizing the RedBook Update – September 2002. New Jersey: Thompson Medical Economics.
® Dose and cost calculated utilizing an estimated patient weight of 70kg. Dose and Cost will vary with actual patient weight.

Maintenance Therapy

Drug	Strength	Cost per Unit *	Route	Dose	Cost per Day*	Cost per Week*#
Vfend® (Voriconazole)	200mg/20mL vial	$ 0.53/mg	Intravenous	4mg/kg every 12 hours	$297.50	$2082.50
Vfend® (Voriconazole)	50mg Tablet	$ 7.81	Oral	100mg every 12 hours	$31.24	$ 218.68
Vfend® (Voriconazole)	200mg tablet	$31.25	Oral	200mg every 12 hours	$62.50	$ 437.50
Sporonox® (Itraconazole)	250mg/25mL vial	$ 0.74/mg	Intravenous	200mg twice a day	$295.80	$ 2070.60
Sporonox® (Itraconazole)	200mg Capsule	$ 8.16	Oral	200mg twice a day	$ 32.64	$228.48
Amphotericin B (generic) *Geneva Brand*	50mg/10mL vial	$ 0.38/mg	Intravenous	1.0 – 1.5 mg/kg/day®	$ 26.60 - $39.90	$186.20 - $ 279.30
Abelcet® (Amphotericin B)	50mg/10mL vial	$ 2.70/mg	Intravenous	5.0 mg/kg/day®	$ 945.00	$ 6615.00
Ambisome® (Amphotericin B)	50mg/10mL vial	$ 3.77/mg	Intravenous	3.0 – 5.0 mg/kg/day®	$ 791.70 – $969.50	$ 5441.90 – $ 6786.50
Amphotec (Amphotericin B)	50mg/10mL vial	$ 1.87/mg	Intravenous	3.0 – 4.0 mg/kg/day®	$ 392.70 – 523.60	$2748.90 – $ 3665.20

* Priced at Average wholesale price (AWP) utilizing the RedBook Update – September 2002. New Jersey: Thompson Medical Economics.
# Duration of therapy should be based on the severity of the patient's underlying disease, recovery from immunosuppression, and clinical response
® Dose and cost calculated utilizing an estimated patient weight of 70kg. Dose and Cost will vary with actual patient weight.

Precipitant Drug	Object Drug*		Description
Voriconazole	Cyclosporine	↑	Coadministration or oral voriconazole increased cyclosporine C_{max} and AUC an average of 1.1 and 1.7 times, respectively. When initiating voriconazole, therapy in patients already receiving cyclosporine, reduce the dose of cyclosporine to 50% the original dose. Frequently monitor cyclosporine levels during coadministraion and when voriconazole is discontinued.
Voriconazole	Ergot alkaloids	↑	Voriconazole may increase the plasma concentrations of ergot alkaloids and lead to ergotism. Coadministration is contraindicated.
Voriconazole	HMG-CoA reductase inhibitors	↑	Voriconazole has been shown to inhibit lovastatin metabolism. Voriconazole may increase the plasma concentrations of statins that are metabolized by the CYP3A4. Consider dosage adjustment of the statin during coadministration.
Voriconazole	Pimozide Quinidine Cisapride	↑	Voriconazole may inhibit the metabolism of these drugs. Increased plasma concentration may lead to QT prolongation and rare occurances of torsades de pointes. Coadministration is contraindicated.
Voriconazole	Prednisolone	↑	Voriconazole may increase the C_{max} and AUC of prednisolone by an average of 11% and 34%, respectively. No dosage adjustment recommended.
Voriconazole	Sirolimus	↑	Voriconazole can significantly increase the C_{max} and AUC of sirolimus by an average of 7-fold and 11-fold, respectively. Coadministration is contraindicated.
Voriconazole	Sulfonylureas	↑	Voriconazole may increase plasma concentrations of sulfonylureas. Monitor for hypoglycemia. Dose adjustment of the sulfonylurea may be needed.
Voriconazole	Tacrolimus	↑	Voriconazole can significantly increase the C_{max} and AUC of tacrolimus an average of 2-fold and 3-fold, respectively. When initiating voriconazole therapy in patients already receiving tacrolimus, reduce the dose of tacrolimus to 33% the original dose. Frequently monitor tacrolimus levels during coadminstration and when voriconazole is discontinued.
Voriconazole	Vinca alkaloids	↑	Coadministration may increase the plasma concentrations of the vinca alkaloids and lead to neurotoxicity. Consider adjusting the dose of the vinca alkaloid and monitor for toxicity.
Voriconazole	Warfarin	↑	Coadministration significantly increased maxiumum prothrombin time about 2 times. Closely monitor coagulation tests and adjust warfarin dose accordingly. Voriconazole may also increase the PT in patients receiving other coumarin anticoagulants.

*↑ = Object drug increased ↓ = Object drug decreased

Drug/Food interactions: When multiple doses of voriconazole are administered with high-fat meals, the mean C_{max} and AUC are reduced by 34% and 24%, respectively.

Dosage and Administration [2,3]

Administration

- Vfend tablets should be taken at least one hour before, or one hour following a meal.
- Vfend IV for injection requires reconstitution to 10mg/mL ans subsequent dilution to 5mg/mL or less prior to administration as an infusion, at a maximum rate of 3 mg/kg per hour over 1-2 hours.

Use in Adults

- Therapy must be initatied with the specified loading dose regimen of intravenous Vfend® to achieve plasma concentrations of Day 1 that are close to steady state. On the basis of high oral bioavailability, switching between intravenous and oral administration is appropriate when clinically indicated.

- For the treatment of adults with invasive aspergillosis due to *Fusarium* spp. and *Scedosporium apiospermum*, the recommended dosing regimen of Vfend is as follows:

  Loading dose:
  - 6mg/kg Vfend® IV every 12 hours for two doses, followed by

  Maintenance dose:
  - 4mg/kg Vfend® IV, every 12 hours

- Once the patient can tolerate medication given by mouth, the oral tablet form of Vfend® (voriconazole) may be utilized.

  Oral maintenance dose
  - ≥ 40kg – 200mg every 12 hours
  - < 40kg – 100mg every 12 hours

Dosage Adjustment

- If patient response is inadequate, the oral maintenance dose may be increased to:
  - ≥ 40kg – 300mg every 12 hours
  - < 40kg – 150mg every 12 hours

- If patients are unable to tolerate treatment, reduce the dose to:
  - Intravenous maintenance dose
    - 3 mg/kg every 12 hours
- Oral maintenance dose by 50mg steps to a minimum of
  - ≥ 40kg – 200mg every 12 hours
  - < 40kg – 100mg every 12 hours

- Phenytoin may be coadministered with Vfend® if the maintenance dose of Vfend® is increased to:
  - Intravenous maintenance dose
    - 5 mg/kg every 12 hours
  - Oral maintenance dose
    - ≥ 40 kg – 200mg to 400mg every 12 hours
    - < 40kg – 100mg to 200mg every 12 hours

Duration of therapy should be based on the severity of the patient's underlying disease, recovery from immunosuppression, and clinical response.

Use in Geriatric Patients

- No dose adjustment is necessary for geriatric patients.

Use in Patients With Hepatic Insufficiency

- In the clinical program, patients were included who had baseline LFTs (AST, ALT) up to 5 times the upper limit of normal. No dose adjustment is necessary in patients with this degree of abnormal liver function, but continued monitoring of LFTs for further elevation is recommended.
- It is recommended that the standard loading dose regimens be used, but that the maintenance dose be *halved* in patients with *mild to moderate hepatic cirrhosis*.

Conclusion [2,3]

Vfend® (voriconazole) is a new primary treatment option for acute invasive aspergillosis, available in both an oral and an intravenous formulation. In clinical trials, both voriconazole formulation (intravenous and oral) have proven to be somewhat effective in comparison to both intravenous amphotericin B and oral itraconazole therapies. Only one study (Study 307/602) evaluated the comparative efficacy between amphotericin B and voriconazole therapy in 277 patients with acute invasive aspergillosis. The mean duration of voriconazole dosing was 76 days (range 2-232 days) as compared 12 days (range 1-85 days) with amphotericin B. A 71% survival rate was seen with voriconazole as compared to 58% with amphotericin B at Day 84.

It is recommended that the patient be initiated on the intravenous formulation of voriconazle for the loading dose portion the treatment and based on clinical response, may then be switched to the oral formulation for maintenance therapy. Duration of therapy with voriconazole is based on the severity of the patient's underlying disease, recovery from immunosuppression, and clinical response. From a cost comparison standpoint, oral voriconazole is priced similarly to both oral itraconazole and generic amphotericin B intravenous therapy. Likewise, the intravenous voriconazole formulation carries a significant cost as do the other intravenous formulations. Although if the typical treatment duration is as stated in

the above trial, it would cost approximately $22,610 to treat a 76-day course with voriconazole as compared to approximaltey $11,340 to treat a 12-day course with the most expensive amphotericin B product. Further studies are warranted as to the cost and clinical effectiveness of voriconazle therapy.

Recommendation(s)

It is recommended that oral Vfend be subject to step-wise therapy following clinical edits.

References

1. Newly approved drug theriapes: Vfend (voriconazole). CenterWatch Clincal Trials Listing Service – Patient Resources. http://www.centerwatch.com/patient/drugs/dru784.html. Available via Internet. Accessed 2002 September 18.
2. Vfend® package insert. New York, NY: Pfizer; 2002 May.
3. Short RM, Burnham TH, et al., editors. Facts and Comparisons. Missouri: Facts and Comparisons.
4. RedBook Update – September 2002. New Jersey: Thompson Medical Economics.

Prepared by: Francine A. Farnsworth, Pharm.D.
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Standard III. Optimizing Medication Therapy

An important responsibility of the pharmacist is optimizing medication use. Pharmacists, in collaboration with medical and nursing staff, shall develop policies and procedures based on demonstrated best practices for ensuring the quality of medication therapy.

A. Creating a Relationship with the Patient

A-1. Pharmacist Role in Direct Patient Care.

- Hospital and pharmacy department policies should encourage pharmacists to provide direct patient care to the greatest extent possible in both inpatient and outpatient settings.
- Hospital and pharmacy department policies should encourage pharmacists to engage in medication therapy management, immunization, medication ordering and administration, and other patient care activities to the extent permitted by law, regulation, and hospital requirements.

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A-2. Continuity of Care.

- Pharmacists should assume responsibility for continuity of care for patients' medication therapy.
- Policies and procedures for admissions, discharges, and transfers so that patients' medication therapy is well managed regardless of patient transitions across care settings.

A-3. Patient Confidentiality.

- Laws and regulations.
- Safeguarding access to all patient information.
- Patient information shall be shared only with authorized health professionals and others authorized within the hospital or health system as needed for the care of patients.
- Pharmacy personnel should periodically receive training in how to comply with patient confidentiality laws and regulations.

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B. Acquiring Essential Patient Data.

- Pharmacists should obtain, prepare, or have immediate access to comprehensive medication histories for each patient, from the patient's medical record or other databases (e.g., a medication profile), or both.
- A pharmacist-conducted medication history for each patient is desirable.
- Electronic medical records should be constructed so that medication histories and other data required for medication management, including medication reconciliation, are available to all health professionals caring for a patient.

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C. Consulting With Other Health Professionals About Medication Therapy.

C-1. Pharmacist's Consultations.

- Pharmacists should provide oral and written consultations to other health professionals regarding medication therapy selection and management.

C-2. Medical Record Documentation.

- There shall be policies and procedures for pharmacist review of and documentation in patients' medical records.
- Recommendations made by the pharmacist and actions taken in response to those recommendations should be documented in the patient's medical record.

C-3. Medication Therapy Decisions.

- The pharmacist initiates, monitors, and modifies medication therapy for individual patients (laws and regulations).

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Standard IV. Drug Product Procurement and Inventory Management

The pharmacy shall be responsible for the procurement, distribution, and control of all drug products used in the hospital for inpatient and ambulatory patients.

A. Selecting Sources of Pharmaceutical Products.

A-1. Medication Acquisition.

- These policies and procedures should address:

✓ formulary development (including initial evaluation for formulary consideration, medication-utilization review programs, and therapeutic interchange).

✓ medication shortages.

✓ cost-effective patient services.

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B. Managing Inventory.

B-1. Medication Storage.

Medications shall be received, stored, and prepared under proper conditions of sanitation, temperature, light, moisture, ventilation and security to ensure medication integrity and personnel safety.

B-2. Drug Shortages.

- The pharmacy's inventory management system should be designed to detect subminimum inventory levels and alert the pharmacy to potential shortages.
- The pharmacy should develop strategies for identifying alternative therapies, working with suppliers, collaborating with physicians and other health care providers, and conducting an awareness campaign in the event of a drug product shortage.

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B-3. Samples.

- The use of medication samples shall be eliminated to the extent possible.
- Medication samples shall never be used for inpatient treatment.
- If use of samples is otherwise permitted, there shall be policies and procedures to ensure their safe use.

B-4. Patient Care Area Stock.

- The proper use of automated dispensing devices reduces the need for medications to be stored in nonpharmacy areas.
- Storage of medications in nonpharmacy areas (e.g., patient care and procedural areas) shall to the extent possible be limited to medications for emergency use and routinely used personal care items (e.g., mouthwash and antiseptic solutions).

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B-5. Controlled Substances.

There shall be policies and procedures to ensure control of the distribution and use of controlled substances and other medications with a potential for abuse.

B-6. Patient's Own Medications.

- Drug products and related devices brought into the hospital by patients shall be identified by pharmacy and documented in the patient's medical record if the medications are to be used during hospitalization.
- They shall be administered only to a prescriber's order and according to hospital policies and procedures, which should ensure the pharmacist's identification and validation of medication integrity as well as the secure and appropriate storage and management of such medications.

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C. Inspecting Storage Areas and Inventory Items.

All stocks of medications shall be inspected routinely to ensure the absence of outdated, recalled, unusable, or mislabelled products.

Storage conditions that would foster medication deterioration, storage arrangements that might con- tribute to medication errors, and other safety issues shall be assessed, documented, and corrected.

D. Returning Recalled, Expired, and Other Unusable Items.

- There shall be a written procedure for the timely handling and documentation of a drug product recall.
- These procedures should include an established process for removing from use any drugs or devices subjected to a recall, notifying appropriate health care professionals, identifying patients who may have been exposed to the recalled medication, and, if necessary, communicating available alternative therapies to prescribers.
- The pharmacy shall be notified of any defective drug products or related supplies and equipment encountered by the nursing or medical staffs.
- All drug product defects should be reported to the reporting program (e.g., JFDA).

Thank you

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