MedWatch The FDA Safety Information and Adverse Event Reporting Program

Over-the-Counter Topical Antiseptic Products: Drug Safety Communication – FDA Requests Label Changes and Single-Use Packaging to Decrease Risk of Infection

[Posted 11/13/2013]

FDA要求特定非處方(OTC)的外用消毒產品改變標籤和包裝，以提升使用安全性。此項要求的原因是病人使用術前或注射前的抗菌產品而造成感染，此情形雖罕見但持續有案例報告。如果使用得當，外用抗菌劑是安全有效的產品，在注射或手術前使用，可降低皮膚上的細菌數量。然而抗菌劑常常因不當使用而被微生物汙染。因此醫療人員和病人應遵守仿單指示以降低感染機率。

「爆發感染與外用抗菌劑污染有關聯」的報告，曾在醫學文獻和CDC提出過。臨床感染案例也已向FDA報告，導致部分產品回收。報告範圍包含局部感染至全身感染致死。FDA已經審視4件死亡案例、5件傷口感染、7件腹膜炎、10件細菌性關節炎、14件置留導管須更換、16件注射部位感染、32件菌血症案例。這些感染情形已證實是抗菌劑被汙染所造成的。被影響的產品包含了所有常用的抗菌成份，包含酒精、iodophors、chlorhexidine gluconate、quaternary ammonium products。與爆發感染相關的微生物有Bacillus cereus、Burkholderia cepacia、Pseudomonas aeruginosa、Achromobacter xylosoxidans、Ralstonia pickettii、Serratia marcescens，和 Mycobacterium abscessus。

建議

為了進一步降低「不當使用而造成感染的風險和抗菌劑被汙染的可能性」，FDA要求廠商以「單次使用」的容器，包裝術前和注射前使用的抗菌劑。

- 為了減少感染的風險，請依照產品仿單指示使用。
- 單次使用容器的抗菌劑僅限使用一次。
- FDA建議醫療人員和病患，打開抗菌產品後不要稀釋。
- 單次使用後，塗藥工具和未使用的溶液應丟棄。

[Posted 11/13/2013]

AUDIENCE: Healthcare Professionals, Risk Managers, Pharmacy

ISSUE: The U.S. Food and Drug Administration (FDA) is requesting label and packaging changes to enhance the safe use of certain over-the-counter (OTC) topical antiseptic products. This request is the result of our ongoing evaluation of infrequent but continuing reports of infections resulting from antiseptic products labeled for preoperative or preinjection skin preparation. When used properly, topical antiseptics are safe and effective products to reduce the number of bacteria on patients' skin prior to surgery or injections. However, most often, contamination of topical antiseptics occurs when organisms are introduced into the product by users. Therefore, health care professionals and patients should follow all label directions to decrease the chances of infection.

Outbreaks associated with the use of contaminated topical antiseptics have been reported in the medical literature and to the Centers for Disease Control and Prevention (CDC). Clinical infections have also been reported to FDA, leading to some product recalls. The reported outcomes ranged from localized infections at injection sites to systemic infections that resulted in death. FDA has reviewed reports of four deaths, five cases of wound infection, seven cases of peritonitis, 10 cases of septic arthritis, 14 cases of indwelling catheters requiring replacement, 16 cases of injection site infection, and 32 cases of bacteremia. These infections have been confirmed to be caused by contaminated antiseptic products. Affected products

included all commonly used antiseptic ingredients, including alcohol, iodophors, chlorhexidine gluconate, and quaternary ammonium products. Organisms implicated in the outbreaks included Bacillus cereus, Burkholderia cepacia, Pseudomonas aeruginosa, Achromobacter xylosoxidans, Ralstonia pickettii, Serratia marcescens, and Mycobacterium abscessus.

BACKGROUND: Over-the-counter (OTC) topical antiseptic drugs for use according to the label instructions to reduce the number of bacteria on the skin prior to surgery or injections. When used properly, over-the-counter (OTC) topical antiseptics are safe and effective products to reduce the number of bacteria on the skin prior to surgery or an injection. Commonly used products contain isopropyl or ethyl alcohol, povidone iodine, poloxamer iodine, benzalkonium chloride, benzethonium chloride, or chlorhexidine gluconate as a single agent or in combination with alcohol. These products are marketed as solutions, swabs, pads saturated with a solution, and applicators containing a solution. Currently available as both single-use and multiple-use products.

Topical antiseptics are not required to be manufactured as sterile and so may become contaminated with bacteria during manufacturing. Labeling stating a product is sterile means it was treated with a process during manufacturing to eliminate all potential microorganisms. However, even topical antiseptics manufactured with a sterile process, can become contaminated if proper care is not taken when using them. The term nonsterile on the product label means it was not sterilized during manufacturing; it does not mean the product contains harmful bacteria.

RECOMMENDATION: To further reduce the risk of infection with improper topical antiseptic use and the possibility of these products becoming contaminated with bacteria during use, we are requesting that manufacturers package antiseptics indicated for preoperative or preinjection skin preparation in single-use containers.

- To reduce the risk of infection, ensure the products are used according to the directions on the label.
- The antiseptics in these single-use containers should be applied only one time to one patient.
- We also recommend that health care professionals and patients do not dilute antiseptic products after opening them.
- Applicators and any unused solution should be discarded after the single application.