

Press Releases

Cluster of Burkholderia cepacia complex infection under DH investigation (with photo)

The Centre for Health Protection (CHP) of the Department of Health (DH) is today (September 18) investigating a cluster of Burkholderia cepacia complex infection affecting 53 renal patients.

The DH received notification from the Hospital Authority (HA) yesterday that the Queen Mary Hospital identified 53 peritoneal dialysis patients who had Burkholderia cepacia complex infection in the past two years. The affected persons involved 24 males and 29 females, aged 24 to 90. Among them, five cases were invasive infections.

According to the environmental surveillance by the HA, some samples of a type of prepacked aqueous chlorhexidine (see photo) acquired from shops in some hospitals, which is also available for sale in local shops and pharmacies, were found to have tested positive for Burkholderia cepacia complex. Prepacked aqueous chlorhexidine is used by peritoneal dialysis patients for skin disinfection and catheter exit site care at home.

Based on the HA's preliminary findings, the DH urges members of the public not to use the product named Pro-Medi Prosept solution for wound care because the product may be contaminated by bacteria.

The product is distributed by Sources (U.S.A.) Medicines Ltd (Sources). The DH has conducted an inspection at Sources today, during which samples of the product were collected for analytical tests. Sources voluntarily recalls the affected product from the market and has also set up a hotline (2411 3463) to answer related enquiries.

Pro-Medi Prosept solution contains 0.05 per cent chlorhexidine, which is not classified as a pharmaceutical product under the Pharmacy and Poisons Ordinance (Cap 138).

The DH has already contacted local private hospitals and registered renal dialysis centres to understand if they observed the emergence of Burkholderia cepacia complex infection among their patients. The DH will also contact the infected cases concerned, if any, for follow-up and investigation. In addition, the DH will issue a letter to inform doctors of the cases of infection, remind them not to use the product in question, and advise them on wound care.

The DH's epidemiological investigation and market surveillance operation on relevant products are still on-going.

"Members of the public, especially those who have weakened immune systems, such as renal patients, should pay extra attention to personal hygiene. Antiseptic products not indicated for wound care should not be used for that purpose or on broken skin. The public should also follow the instructions given by healthcare workers on wound care," a spokesman for the DH said.

"Burkholderia cepacia is a bacteria which is commonly found

in water, soil, and moist environments. It is generally not pathogenic to healthy person but those who have weakened immune systems or chronic lung diseases may be more susceptible to infection with the bacteria," the spokesman explained.

Ends/Wednesday, September 18, 2019
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Press Releases

Update on Burkholderia cepacia complex infection (with photo)

The Department of Health (DH) today (September 19) reported an update on its investigations into the cluster of Burkholderia cepacia complex infection announced yesterday and further urged members of the public not to use a product named Kam's KS-MED solution (see photo) for wound care as it may be contaminated by bacteria.

Ongoing investigations of the Centre for Health Protection (CHP) of the DH since first notification yesterday by the Hospital Authority (HA) have identified an additional 117 and 11 renal dialysis patients who were diagnosed as having Burkholderia cepacia complex infection in the past two years by public hospitals and private hospitals respectively.

As of today, a total of 181 patients were known to be affected, comprising of 84 males and 97 females aged 24 to 100. Epidemiological investigations are ongoing.

Meanwhile, the DH received notification from the HA on an incidental finding about another prepacked aqueous chlorhexidine product named Kam's KS-MED solution which tested positive for Burkholderia cepacia complex.

Based on the HA's findings, the DH urges members of the public not to use the product, which is available for sale in shops in some hospitals, local shops and pharmacies for wound care.

The product is distributed by Kam Sing Medicine Co. (Kam Sing). The DH conducted a joint operation with Hong Kong Customs at Kam Sing in Tai Kok Tsui today during which samples of the product and related materials were collected for analytical tests. In the operation, Customs seized 495 sachets of the product bearing suspected false claim of origin with a total estimated market value of about \$990. A 72-year-old male sole proprietor of the company was also arrested. Investigations by the DH and the Customs are ongoing.

Kam's KS-MED solution contains 0.05 per cent chlorhexidine gluconate and is labelled "Non-medicine product". Therefore, it should not be used for wound care or on broken skin. As a precautionary measure, Kam Sing has voluntarily recalled the product from the market and has also set up a hotline (2392 7537) to answer related enquiries during office hours.

Currently, products containing a low concentration of chlorhexidine not labelled for use on broken skin or wound care are not classified as pharmaceutical products under the Pharmacy and Poisons Ordinance (Cap 138). The DH will continue to conduct market surveillance on similar products available on the market.

"Members of the public, especially those who have a weakened immune system, such as renal patients, should pay extra attention to personal hygiene. Antiseptic products not indicated for wound care should not be used for that purpose or on broken skin. The public should also follow the instructions given by healthcare professionals on wound care and should seek medical

advice if in doubt," a spokesman for the DH said.

"According to the Infection Control Guidelines on Nephrology Services in Hong Kong, sterile solution of 0.9 per cent sodium chloride or antiseptic solution (e.g. aqueous chlorhexidine 0.05 per cent) can be used for peritoneal catheter exit site cleansing," the spokesman said.

"Normal saline (solution of 0.9 per cent sodium chloride) is a commonly used cleansing fluid. As it is similar to human body fluid, it does not irritate wound tissues and causes less pain when applied. Antiseptics may irritate the wound or cause an allergic reaction. Generally, a non-infected wound could be cleansed with normal saline and antiseptics are not required, while an infected wound must be managed according to a doctor's instructions," the spokesman added.

Under the Trade Descriptions Ordinance, any person who supplies goods with a false trade description in the course of trade or business, or has in possession of any goods for sale with a false trade description, commits an offence. The maximum penalty upon conviction is a fine of \$500,000 and imprisonment for five years.

For more information on wound care, please visit www.elderly.gov.hk/english/healthy_ageing/home_safety/wound_care.html.

Ends/Thursday, September 19, 2019
Issued at HKT 22:28

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Press Releases

Update on Burkholderia cepacia complex infection (with photo)

The Department of Health (DH) today (September 20) announced an update on its investigations into the cluster of Burkholderia cepacia complex infection and further urged members of the public not to use a product named CANCARE AntiSept Solution (see photo) for wound care as it may be contaminated by bacteria.

As at 4pm today, the DH's Centre for Health Protection has recorded no additional patients being affected under the cluster. Meanwhile, the DH received the latest notification from the Hospital Authority that apart from the aqueous chlorhexidine products named Pro-Medi Prosept and Kam's KS-MED announced earlier, another product named CANCARE AntiSept Solution also tested positive for Burkholderia cepacia complex.

The product is distributed by C & L Pharmaceutical Ltd. The DH has conducted an inspection at the company today, during which samples of the product were collected for analytical tests. C & L Pharmaceutical Ltd voluntarily recalls the affected product from the market and has also set up a hotline (2475 9168) to answer related enquiries.

CANCARE AntiSept Solution contains 0.05 per cent chlorhexidine, which is not classified as a pharmaceutical product under the Pharmacy and Poisons Ordinance (Cap 138).

Currently, products containing a low concentration of chlorhexidine not labelled for use on broken skin or wound care are not classified as pharmaceutical products under the Ordinance. Nevertheless, the DH has strengthened market surveillance and collected products containing a low concentration of chlorhexidine from different brands for micro-organism tests in batches. The tests will take about a few weeks and results will be announced as soon as possible.

Currently, the following three antiseptic products are being recalled:

Distributor	Product name	Hotline
Sources (U.S.A.) Medicines Ltd	Pro-Medi Prosept solution	2411 3463
Kam Sing Medicine Co.	Kam's KS-MED solution	2392 7537
C & L Pharmaceutical Ltd	CANCARE AntiSept Solution	2475 9168

The DH's investigations are still on-going.

"Members of the public, especially those who have a weakened immune system, such as renal patients, should pay extra attention to personal hygiene. Registered pharmaceutical products should be used and instructions given by healthcare professionals should be followed if they need to carry out wound care on their own. Antiseptic products not indicated for wound care should not be used for that purpose or on broken skin. The public should seek medical advice if in doubt," a spokesman for the DH said.

"According to the Infection Control Guidelines on Nephrology Services in Hong Kong, sterile solution of 0.9 per cent sodium chloride or antiseptic solution (e.g. aqueous chlorhexidine 0.05 per cent) can be used for peritoneal catheter exit site cleansing," the spokesman said.

"Normal saline (solution of 0.9 per cent sodium chloride) is a commonly used cleansing fluid. As it is similar to human body fluid, it does not irritate wound tissues and causes less pain when applied. Antiseptics may irritate the wound or cause an allergic reaction. Generally, a non-infected wound could be cleansed with normal saline and antiseptics are not required, while an infected wound must be managed according to a doctor's instructions," the spokesman added. For more information on wound care, please visit www.elderly.gov.hk/english/healthy_ageing/home_safety/wound_care.html.

Members of the public can refer to the appendix for information on registered antiseptic pharmaceutical products containing chlorhexidine as well as sterile saline solution for irrigation. All registered pharmaceutical products should carry a Hong Kong registration number on the package in the format of "HK-XXXXX". People should seek advice from healthcare professionals before using pharmaceutical products.

Meanwhile, the Pharmacy and Poisons Board of Hong Kong today held a meeting during which members reviewed the current classification of antiseptic products containing a low concentration of chlorhexidine under the Ordinance. Members decided to review, making reference to overseas regulatory practice of such antiseptic products, and consider whether such consumer goods should be regulated as registered pharmaceutical products.

Ends/Friday, September 20, 2019
Issued at HKT 20:12

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Press Releases

Update on Burkholderia cepacia complex infection (with photos)

The Department of Health (DH) today (September 23) announced an update on its investigations into the cluster of Burkholderia cepacia complex infection.

As at 4pm today, the DH's Centre for Health Protection has recorded a total of 184 patients known to be affected, comprising of 85 males and 99 females aged 24 to 100. Epidemiological investigations are ongoing.

In addition, according to the latest notification by the Hospital Authority, apart from the aqueous chlorhexidine products named Pro-Medi Prosept, Kam's KS-MED and CANCARE AntiSept Solution announced earlier, two products named Smart Medi Chlorhexidine Antiseptic Solution and Dr. MAX'S Chlorhexidine Antiseptic Solution (see photos) were also tested positive for Burkholderia cepacia complex. Another product, namely 0.05% Chlorhexidine Gluconate Antiseptic Sanitize (KS Medical) (see photo) was tested positive for Achromobacter. These products contain 0.05 per cent chlorhexidine, which are not classified as pharmaceutical products under the Pharmacy and Poisons Ordinance (Cap 138).

Smart Medi Chlorhexidine Antiseptic Solution and Dr. MAX'S Chlorhexidine Antiseptic Solution are distributed by Sources (U.S.A.) Medicines Ltd (Sources). Meanwhile, 0.05% Chlorhexidine Gluconate Antiseptic Sanitize (KS Medical) is distributed by Kam Sing Medicine Co. (Kam Sing). Sources and Kam Sing have also set up hotlines to answer related enquiries during office hours (please refer to the table below).

Currently, the following six antiseptic products are being recalled:

Distributor	Product name	Hotline
Sources (U.S.A.) Medicines Ltd	Pro-Medi Prosept solution	2411 3463 2411 3182
	Smart Medi Chlorhexidine Antiseptic Solution	
	Dr. MAX'S Chlorhexidine Antiseptic Solution	
Kam Sing Medicine Co.	Kam's KS-MED solution	2392 7537
	0.05% Chlorhexidine Gluconate Antiseptic Sanitize (KS Medical)	
C & L Pharmaceutical Ltd	CANCARE AntiSept Solution	2475 9168

Currently, products containing a low concentration of chlorhexidine not labelled for use on broken skin or wound care are not classified as pharmaceutical products under the Ordinance. Members of the public should not use these products for wound care or on broken skin. The Pharmacy and Poisons Board of Hong Kong will make reference to overseas regulatory practice of such antiseptic products and consider whether such consumer goods should be regulated as pharmaceutical products. The DH has also strengthened market surveillance and collected products

containing a low concentration of chlorhexidine from different brands for micro-organism tests in batches. The tests will take about a few weeks and results will be announced as soon as possible.

The DH's investigations are still on-going.

"Members of the public, especially those who have a weakened immune system should pay extra attention to personal hygiene. Registered pharmaceutical products should be used and instructions given by healthcare professionals should be followed if they need to carry out wound care on their own. The public should seek medical advice if in doubt," a spokesman for the DH said.

"Normal saline (solution of 0.9 per cent sodium chloride) is a commonly used cleansing fluid. As it is similar to human body fluid, it does not irritate wound tissues and causes less pain when applied. Antiseptics may irritate the wound or cause an allergic reaction. Generally, a non-infected wound could be cleansed with normal saline and antiseptics are not required, while an infected wound must be managed according to a doctor's instructions," the spokesman added. For more information on wound care, please visit www.elderly.gov.hk/english/healthy_ageing/home_safety/wound_care.html.

"Achromobacter, similar to Burkholderia cepacia, is a bacteria which is commonly found in the environment. It is generally not pathogenic to healthy person, but can cause infections in persons who have weakened immune system. So far, the CHP has not recorded relevant infection cases," the spokesman explained.

Members of the public can refer to the appendix for information on registered antiseptic pharmaceutical products containing chlorhexidine as well as sterile saline solution for irrigation. All registered pharmaceutical products should carry a Hong Kong registration number on the package in the format of "HK-XXXXX". People should seek advice from healthcare professionals before using pharmaceutical products.

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List of registered pharmaceutical products containing chlorhexidine solution

	<u>Product Name</u>	<u>Active Ingredients</u>	<u>HK No.</u>
1	Hibicet Hospital Concentrate	1. chlorhexidine gluconate 1.5%w/v, 2. cetrimide 15%w/v	HK-06769
2	Salo Antiseptic Liquid	1. chlorhexidine gluconate 0.3%w/v, 2. cetrimide 3%w/v	HK-19916
3	Microshield 5 5% Chlorhexidine Conc Soln	chlorhexidine gluconate 5%w/v	HK-37070
4	0.015% Chlorhexidine & 0.15% Cetrimide Sol	1. chlorhexidine acetate 0.015%w/v, 2. cetrimide 0.15%w/v	HK-42682
5	0.05% Chlorhexidine & 0.5% Cetrimide Sol	1. chlorhexidine acetate 0.05%w/v, 2. cetrimide 0.5%w/v	HK-42684
6	Chlorhexidine Antiseptic Soln 0.05%	chlorhexidine acetate 0.05%w/v	HK-42687
7	Chlorhexidine Solution 5%	chlorhexidine gluconate 5%w/v	HK-45791
8	Chlorhexidine Conc Solution 20%	chlorhexidine gluconate 20%w/v	HK-45792
9	Riotane Concentrate Soln. 5%	chlorhexidine gluconate 5%w/v	HK-48347
10	Baxedin 2%-70% Solution	1. chlorhexidine gluconate 2%w/v, 2. isopropyl alcohol 70%v/v	HK-58765

List of registered pharmaceutical products containing normal saline solution for irrigation

	<u>Product Name</u>	<u>Active Ingredient</u>	<u>HK No.</u>
1	Sodium Chloride Solution 0.9% w/v (Guangdong Otsuka)	sodium chloride 0.9%w/v	HK-43625
2	Sodium Chloride Irrigation USP	sodium chloride 0.9%w/v	HK-44288
3	Sodium Chloride Solution For Irrigation 0.9%	sodium chloride 0.9%w/v	HK-48735
4	Sodium Chloride Irrigation 0.9%	sodium chloride 0.9%w/v	HK-50317
5	Sodium Chloride Irrigation Solution 0.9% W/V	sodium chloride 0.9%w/v	HK-66256