

Prepacked aqueous chlorhexidine product contaminated with *Burkholderia cepacia* complex (BCC): Situation analysis

Ad hoc Meeting of WG of Collaboration between
CHP and Private Hospitals on Safe Use of
Antibiotics & Infection Control

24 Sept 2019



Background

- QMH identified *Burkholderia cepacia* complex (BCC) from the clinical specimens collected from the catheter exit site of four renal patients on 6 September.
 - Two brands of chlorhexidine antiseptic currently used by the public hospitals and clinics were negative for the bacteria,
 - while the **prepacked aqueous chlorhexidine, sampled from the community pharmacies and healthcare product shops in some hospitals, had tested positive for BCC**
- A retrospective review of peritoneal dialysis patients by QMH found that
 - 53 patients have BCC infection in the last two years, including five cases of invasive infections.
 - There is currently no evidence that any of the patients died of the infection



新聞稿 PRESS RELEASE

Wednesday, 18 September 2019

Renal Units and Patients Alerted on Unusual Infection Identified in Renal Patients

The Hospital Authority (HA) today (18 September) advised renal patients to be cautious with the use of antiseptics for wound care at home, following a notification from Queen Mary Hospital (QMH) yesterday on an outbreak of *Burkholderia cepacia* complex infection of renal dialysis patients.

The HA spokesperson said that QMH identified *Burkholderia cepacia* complex from the clinical specimens collected from the catheter exit site of four renal patients on 6 September. An environmental surveillance was initiated immediately to ascertain whether there was a common source of infection.

“The environmental surveillance confirmed that the two brands of chlorhexidine antiseptic currently used by the public hospitals and clinics were negative for the bacteria, while the prepacked aqueous chlorhexidine, sampled from the community pharmacies and healthcare product shops in some hospitals, had tested positive for *Burkholderia cepacia* complex.”

Prepacked aqueous chlorhexidine is used by some renal dialysis patients for skin disinfection and catheter exit site care at home, and can be purchased over-the-counter in community pharmacies and healthcare product shops.

“A retrospective review of peritoneal dialysis patients by QMH found that 53 patients have *Burkholderia cepacia* complex infection in the last two years, including five cases of invasive infections. There is currently no evidence that any of the patients died of the infection.”

The HA spokesperson said that the HA Central Renal Committee had issued an alert to all renal units on the incident and patients would be reminded to follow the instructions from respective renal unit on catheter exit site care at home.

“The HA will review the laboratory results of renal patients with *Burkholderia cepacia* complex infection in all public hospitals in due course, while patients are advised to seek medical advice if wound infection is suspected. Healthcare product shops in public hospitals have also been informed of the incident and to suspend selling the antiseptic concerned.”

“The findings by QMH have been reported to the Department of Health for follow up and we will co-operate with DH on the epidemiological investigation if needed,” the spokesperson added.

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Situation updates (as at 23 Sept 2019)

- A total of 184 patients known to be affected, comprising of 85 males and 99 females aged 24 to 100
- Five aqueous CHG products contaminated with BCC
 - Pro-Medi Prosept (reported on 18 Sept)
 - Kam's KS-MED (reported on 19 Sept)
 - CanCare AntiSept Solution (reported on 20 Sept)
 - Smart Medi Chlorhexidine Antiseptic Solution (reported on 23 Sept)
 - Dr. MAX'S Chlorhexidine Antiseptic Solution (reported on 23 Sept)
- One was tested positive for Achromobacter
 - 0.05% Chlorhexidine Gluconate Antiseptic Sanitize (KS Medical) (reported on 23 Sept)



DH actions

- Issued Press Release on [18](#), [19](#), [20](#) & [23](#) Sept 2019
- Issued Letters to Doctors on [18](#), [19](#), & [20](#) Sept 2019
- Issued Letters to RCHEs on 20 Sept 2019
- Issued Letters to RCHDs / DTRCs on 24 Sept 2019
- DH has strengthened market surveillance and collected products containing a low concentration of chlorhexidine from different brands for micro-organism tests.
 - The tests will take about a few weeks and results will be announced as soon as possible.



Health advices on wound care

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



Advice on peritoneal catheter exit site care

- For peritoneal catheter exit site cleansing, according to the [Infection Control Guidelines on Nephrology Services in Hong Kong](#),
 - Use normal saline (0.9% saline) or antiseptic solution (e.g. aqueous chlorhexidine 0.05%) for peritoneal catheter exit site cleaning



Highlights about chlorhexidine containing products

- 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)
 - should not use these products for wound care or on broken skin.
- The Pharmacy and Poisons Board of Hong Kong held a meeting on 20 Sept 2019,
 - 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



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

Extracted from [press release on 23 Sept 2019](#)

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

Extracted from [press release on 23 Sept 2019](#)

End

