

Outbreak of *Ralstonia pickettii* bacteremia in a medical center of Taiwan

A medical center of Taiwan discovered an abnormal increase of *Ralstonia pickettii*; the initial investigation showed all cases used 20ml normal saline (NS) injections from a specific lot number (273A79D) of a manufacturer. Besides stopping the use of 273A79D NS solution and initiating a recall, the medical center informed the Taiwan Food and Drug Administration (TFDA) of the event. TFDA held a press conference to make the lot number and the shipment list public, as well as ordered a recall and requested healthcare facilities and pharmacies to pull all 273A79D NS products off the shelves within 24 hours. On the other hand, the Taiwan Centers for Disease Control (TCDC) conducted a purposive sampling and hospital investigation to eliminate possibilities of nosocomial infection, laboratory contamination and others. This event demonstrates the collaborations of clinical infection control unit, laboratory and public health system are important in identifying infection source and lowering the impact to the public.

Lot No.	No. of NS solution samples collected	No. of samples tested	No. of samples positive with <i>Ralstonia pickettii</i>
273A79D*	28	16	3
273A08D	5	3	0
273A68D	5	3	0
273A78D	5	3	0
273A80D	5	3	0
273A84D	5	3	0
Total	53	31	3
*The lot number that all cases in this outbreak event have used.			

Tab. 1. Test results of the recalled 20-mL normal saline (NS) solution of the reporting medical center that have been collected and tested by Taiwan CDC.

In order to clarify whether the event was caused by the product or other problems, the investigations conducted by TCDC and the findings are as following:

TCDC requested healthcare facilities to report if they have used or stockpiled 273A79D NS solution and other products from the same manufacturer and whether any clinical specimen had been identified with *Ralstonia pickettii* between April 20 and May 31, 2015. Among the 490 healthcare facilities reported back, 133 of them have used NS produced by the same manufacturer and 9 of them have used 273A79D NS solution. No hospital that has used the same NS solution reported any incidence of *Ralstonia pickettii* infection except the reporting medical center.

TCDC visited the reporting medical center to update the status of the epidemiological investigation and the condition of infected patients. Additionally, to eliminate the possibilities of nosocomial infection, contamination at the laboratory operations and others, TCDC conducted a further investigation regarding the recall condition and standard operation procedures of infection control and laboratory. TCDC also requested the reporting medical center to continue monitoring any increasing positive case of *Ralstonia pickettii* infection. In total, 25 positive cases were identified dated to June 3, 2015, which were from multiple units in the reporting medical center. Besides using the same 273A79D products, no common medical procedures were identified among these cases.

To confirm that the test results of *Ralstonia pickettii* cultured by the reporting medical center were unquestionable and the outbreak was caused by the 273A79D NS products, TCDC conducted a sampling survey. Samples of the 273A79D NS solution and its neighboring lots products, which have the same size, were also recalled by TFDA were collected from the 10 wards of *Ralstonia pickettii* blood culture positive patients. The entire sampling process was verified by the reporting medical center, and all samples were sent to TCDC for testing. Number of samples tested and the results are shown in Table 1. Only 3 samples were cultured positive with *Ralstonia pickettii*, which were all form sealed products of 273A79D collected from the wards of positive cases. TFDA have also identified the same bacteria from the recalled products of 273A79D. In consideration of the results from 3 independent laboratories (the reporting medical center, TFDA and TCDC) and hospital investigations, we concluded the 273A79D products were contaminated with *Ralstonia pickettii* during the manufacturing process and excluded the possibilities of nosocomial infection or laboratory contamination.

The event of *Ralstonia pickettii* outbreak shows the collaborations of the clinical infection control unit, the laboratory department and the public health system are important to assist in early source identification, preventing infection cases from increasing, and lowering the impact to the entire society.

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