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## Letter to the Editor

# A need for a global alert system for rapid recall of contaminated products to prevent ongoing hospital outbreaks

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To the Editor – Hospital outbreaks traced back to products and devices contaminated during the manufacturing process continue to plague us and may even be underrecognized.[1–3] Mouthwash and ultrasound gels contaminated with *Burkholderia cepacia complex* during manufacturing have been recalled in Singapore.[2,4]

We report an outbreak of *Pseudomonas aeruginosa* (PA) identified in the Surgical Intensive Care Unit (SICU) on March 3, 2022. Unbeknownst to us at the time, the source was a new lot of contaminated wet wipes that had replaced older stock on February 22, 2022. Despite extensive microbiological and epidemiologic investigation, aggressive cleaning, audits and closing of infection control gaps, colonization and clinical cases continued to increase in several ICUs through May (Figure 1).

Forty-five isolates (including the 12 from SICU) collected from clinical and surveillance swabs from all ICUs between March and May 2022 were available to be sent for whole genome sequencing (WGS). Of these, 26 (58%) were the outbreak strain ST3875 – 12 respiratory, 9 sterile sites (blood or Cerebrospinal Fluid), and 5 other specimens. Out of the 9 sterile site isolates, there were 4 deaths in which PA was a possible contributory factor, in addition to other serious conditions.

On May 9, PROMED reported on a 6-month-long outbreak of PA in multiple hospitals in Norway linked to contaminated wet wipes, published in Eurosurveillance on May 5.[5] We read this email on May 11, and realized the wet wipes described were from the same manufacturer as those recently introduced at our hospital in Singapore, but under a different brand name.

A voluntary recall of our wet wipes was undertaken and all other hospitals, long-term care facilities, and licensed clinics in Singapore were notified. Singapore's Health Sciences Authority directed the local distributor to conduct a Class 1 recall (a recall of high urgency) of the affected products and published an alert on their website. Fourteen unopened packets of wipes were cultured and demonstrated a heavy growth of wild-type PA within 12 hours. By May 13, all the wipes were removed, and our PA cases fell quickly to baseline. For the SICU, the incidence rate of all PA specimens was 12.2 per 1,000 patient days before the outbreak and 53.7 per 1,000 patient days during the outbreak period, giving an incidence rate ratio of 4.39 ($P$ <0.001) within the outbreak period compared to before the outbreak period.

WGS analysis linked the wipes to the clinical isolates, differing by 0–6 Single-Nucleotide Polymorphisms, identifying both as ST3875, the novel strain identified in the Norwegian outbreak. None of the 16 PA isolates from stored blood cultures collected between February 2021 and February 2022 was ST3875, confirming this was a new genotype in National University Hospital.

Wet wipes and most of our hospital supplies are contracted through a local distributor and not directly from the manufacturer. While a voluntary recall notice dated April 21 for the wipes (including all brand names) was posted on the manufacturer's company website, the local distributor remained unaware of the recall until this event.[6] There is a clear gap in communication and in responsibility for removing recalled products from the delivery chain, given that these chains generally involve multiple parties.

Recall notices and outbreak alerts from Eurosurveillance, PROMED, and national authorities are passive and rely on astute individuals and an element of luck. The WHO's Global Surveillance and Monitoring System is a passive platform for regional and international sharing of defective products, but this system does not cover contaminated cosmetic wipes. We cannot find evidence of a strong proactive global system that ensures prompt notification to countries regarding the withdrawal of contaminated or defective products that could cause serious harm. It is not well-defined if the responsibility lies with the WHO, the International Health Regulation system, manufacturers, or distributors. Once the issue is identified at the national level, there is a greater likelihood of reliable withdrawals of faulty, contaminated, or otherwise dangerous products in that country.

Manufacturing and supply chains are global and so diverse that recipient countries' oversight of manufacturing and safety processes is not practicable, emphasizing the importance of rapid communications between manufacturers, distributors, and regulatory agencies. Moreover, proper oversight of manufacturing quality control of culture results for specific pathogens should preempt potential outbreaks. Consideration should be given to a

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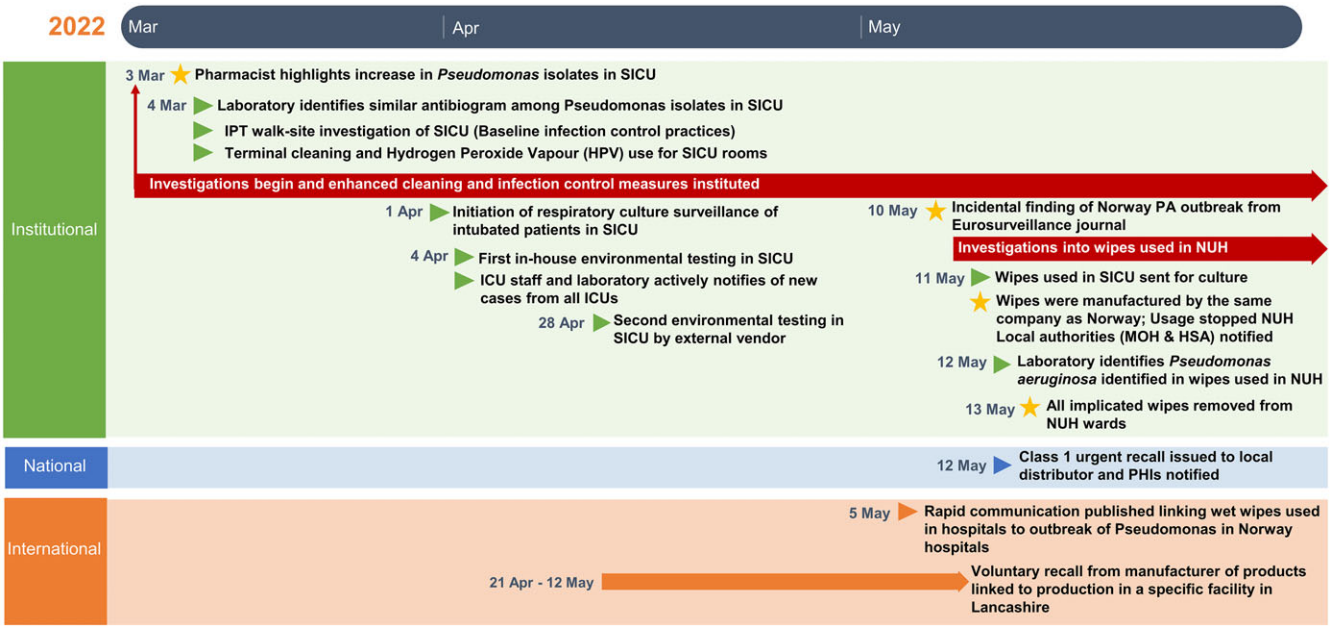


**Figure 1.** Timeline of investigation into increase of *Pseudomonas aeruginosa* cases in Surgical Intensive Care Unit, 3 March to 13 May 2022.

country-level independent agency to review mandatory culture reports for contamination at the manufacturing plant prior to distribution. Clear lines of accountability to an independent regulatory body throughout the manufacturing process are needed to ensure compliance with established quality guidelines.[7–9]

This outbreak also highlights that the introduction of products contaminated with pathogens into the patients' environment or body surfaces can quickly increase the risk of serious infection. Cosmetic and some medical-grade products are not meant to be sterile but must be free of pathogenic bacteria. It may be prudent to avoid the use of these cosmetic or medical-grade, non-sterile products in the ICU setting.

In Norway, the wipes were first banned on March 23, 2022 but they persisted in Singapore hospital inventories until May 13, 2022 despite a passive recall notice on the manufacturer's website dated April 21, 2022.[5,6,10] This outbreak could have been shortened had a system for the rapid dissemination of product recall information existed between countries. If an outbreak occurs implicating a product in one country, rigorous active communication must be systematized to proactively ensure rapid recalls on a global scale through communications within distribution networks and regulatory agencies worldwide.

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