

# Contaminated mouth swabs caused a multi-hospital outbreak of *Pseudomonas aeruginosa* infection

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*Pseudomonas aeruginosa* is a gram-negative, obligate aerobic rod-shaped bacterium with minimal nutritional requirements. It is often found in moist environments and can cause infections in immunocompromised or otherwise-susceptible hosts (1, 2). Numerous outbreaks have been associated with faulty or unclean medical equipment or products (3–9) and with personnel and environmental reservoirs (10–16), as well as with cross-contamination within the hospital (13, 17, 18).

Hospital-acquired infections are costly for society, because of patient suffering and are partly preventable. *Pseudomonas* spp. are ranked among the top 10 causes of bacteraemias in hospitals (19–24). Medical devices have often caused outbreaks.

In late February 2002, the Norwegian Institute of Public Health (NIPH) was alerted to a possible increase in the number of *Pseudomonas* infections in the clinical wards of Norwegian hospitals, especially in intensive care units (ICUs). Infection control personnel in different hospitals had vague impressions of seeing more *Pseudomonas* infections than normal. On 8 March 2002, investigators at St. Olav's Hospital in Trondheim, Norway, discovered genotypically identical strains of *P. aeruginosa* in patient samples from two hospitals in different regions, and 10 days later, they discovered a genotypically identical strain from a third hospital in yet another region. A national outbreak investigation was launched.

The outbreak strain of *P. aeruginosa* was traced to a mouth swab called Dent-O-Sept. This is a clean, non-sterile, moist sponge-on-a-stick produced in Norway, which according to the Norwegian text on the wrap is an antiseptic single-use swab for mouth hygiene (Fig. 1).

The research originates from the results of the outbreak investigation. From it, four areas were explored: (1) the outbreak investigation; (2) the contamination of the medical device involved; (3) theories for causality of the outbreak; and (4) the epidemiology of invasive *P. aeruginosa* infection.

*Paper I* (25) describes the outbreak investigation of *P. aeruginosa* infections, in particular how a nationwide, multicentre investigation was organised and conducted. The team work and combination of epidemiological and microbiological methods were essential in finding the cause and stopping the outbreak. A total of 231 patients from 24 hospitals were identified with the outbreak strain of *P. aeruginosa*; 71 of them died while hospitalised, and for 34 the *Pseudomonas* infection probably contributed to the patients' deaths. Genotypically identical strains of the bacterium were isolated from patients, several batches of the Dent-O-Sept swab and from the production plant. We concluded that susceptible patient groups should use only documented quality-controlled, high-level disinfected products and items in the oropharynx.

*Paper II* (26) describes the investigation of the swabs, the moisturising liquid and the production facility. A total of 76 swabs from 12 different batches produced over a period of 30 weeks were contaminated with the outbreak strain of *P. aeruginosa*. Many swabs were also contaminated with other microbes. More than 250 of 1,565 examined swabs were contaminated with one or more microbial species. A system audit revealed serious breaches of production regulations. Biofilm formation in the wet part of the production was proposed as the most plausible explanation for the continuous contamination of the swabs. The legal requirements for microbiological purity of medical devices in Class 1 are not optimal.

*Paper III* (27) explores the theories for causality of the outbreak of *P. aeruginosa* infections. Applying various theories for causality and responsibility from different fields, such as science, philosophy and law on the actors and acts involved in the outbreak helped elucidating their roles and responsibilities, especially legal theories and counterfactual reasoning. We concluded that many factors contributed to causing the outbreak, but that contamination of a medical device in the production facility was the major necessary condition. The reuse of the medical device in hospitals contributed primarily to the size of the outbreak. In addition, there were many errors in the chain from the production of the swabs,



**Fig. 1.** The Dent-O-Sept swab is a clean, non-sterile, premoisted sponge-on-a-stick, which according to the Norwegian text on the wrap is an antiseptic single-use swab for mouth hygiene.

through purchasing and storage systems in the health care institutions to the use of the swabs and reporting of defective devices. The unintended error by its producer – and to a minor extent by the hospital practice – was mainly due to non-application of relevant knowledge and skills, and appears to constitute professional negligence. Due to factors outside the discourse of causality, no one was criminally charged for the outbreak.

*Paper IV* (28) investigates the epidemiology of invasive *P. aeruginosa* infection in Norway. Although *P. aeruginosa* usually does not cause infection in healthy persons, it frequently does in patients with certain underlying diseases, and in patients with disrupted barriers, especially in the ICU. Invasive *P. aeruginosa* infection is a rare disease with an incidence rate of 3.16 per 100,000 person-years at risk or 0.20 per 1,000 hospital stays, but very serious for those contracting it with a 30-day case fatality rate of 33%. Patients with malignant neoplasms of lymphoid and haematopoietic tissue and other diseases of blood and blood-forming organs have the highest risk of infection. Prudent antibiotic use is one possible explanation for much lower rates of infection in Norway compared with all other published studies.

### Lessons learned

Medical devices, moist equipment and solutions and moist environments are frequently associated with outbreaks with *P. aeruginosa* and related moisture-prone bacteria. Lack of adherence to standard precautions for infection control and prevention by hospital personnel contributes to the propagation of these outbreaks.

Biofilm formation is possibly the more common of the two distinct modes of behaviour for bacteria; the other being the planktonic mode (29–31). Bacterial biofilms are less sensitive to disinfection and make it more difficult to eradicate. Not abiding by the production regulations,

e.g. the requirement to have quality assurance systems including an effective microbiological control system, made the contamination possible in the production process.

Outbreak investigations are essential to detect causes of an outbreak and to gain experience in order to prevent their recurrence. Investigating large, multicentre outbreaks is resource demanding and necessitates a defined network structure where everyone knows their role and qualifications and try utmost to cooperate. Expertise in a variety of fields is essential. Molecular finger-printing techniques to identify the outbreak strain of the microbe and discriminate against other strains have become an indispensable part of most outbreak investigations.

This outbreak has necessitated a reassessment of the guidelines for preventing infection in critically ill and otherwise-susceptible patients. Oropharyngeal colonisation is important for the development of ventilator-associated pneumonia, and oral care may prevent pneumonia, but few have addressed whether oral products other than ventilators or nebuliser equipment need to be sterile or subjected to high-level disinfection for this patient group. We conclude that sterility is not necessary for such products, but only items for which the manufacturer can document that quality control and high-level disinfection have been performed (including tap water and moist products) should be used in the oropharynx for susceptible patient groups.

### Conflict of interest and funding

There is no conflict of interest in the present study for the author. All primary costs were covered by the health care institutions and national bodies involved. Costs for genotyping of *Pseudomonas aeruginosa* was refunded by the Norwegian Ministry of Health.

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