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Law Notes

Norway: The Case of Dent-O-Sept

Norwegian Inspectorate of Public Health: Rapport til Helsedepartementet om Helsetilsynets oppfølging I Dent-O-Sept saken. (Report to the Department of Health on the Inspectorate's handling of the Dent-O-Sept case.) Oslo, November 2003

In late 2001 and early 2002 outbreaks of hospital infection with *Pseudomonas aeruginosa* were reported in a number of hospitals in Norway, primarily involving intensive care units. In all the organism was found in 231 patients; it was present in the blood or spinal fluid in 40 of these individuals. 71 of the patients died while in hospital, and seven others were found to have related complications. While 21 of the deaths were probably due to other causes, in the remainder the link between the infection and the death was either proven or could not be excluded. The infection was traced bacteriologically in the majority of cases to the use of an oral hygiene product known as Dent-O-Sept which had been employed in most of the patients concerned; the remaining cases of infection appeared to have been acquired from Dent-O-Sept indirectly, e.g. with transfer through hospital personnel or contaminated utensils. Many cases had occurred shortly after the release onto the market of a number of batches of Dent-O-Sept which were heavily contaminated with *Pseudomonas*, corresponding to the organisms found in the patients concerned.

Dent-O-Sept was supplied in the form of individually packed disposable spatulas, each tipped with foam rubber, the latter being impregnated with a mildly antiseptic aqueous solution. The latter contained 3.2% ethanol, 9.3% glycerol and 0.18% sodium benzoate; in addition there were small quantities of polyethylene glycol, hydrogenated castor oil, polypropylene glycol, peppermint oil, eugenol, anethole and geranium, in all comprising 1.7% of the content. The product was supplied by a local manufacturer (Messrs Snøgg) and had for many years been used as an aid to oral hygiene in immobilized, seriously ill or dying patients. The individual packages bore a CE emblem and Dent-O-Sept was classified as a medical aid product; it was not claimed to be sterile. Because of the outbreak of problems, the supply and production were prohibited by the Norwegian health authorities in April 2002. The present report into the event constitutes an examination by an expert group of the facts in this case, primarily with respect to the responsibility and liability in this matter of the health authorities dealing with the outbreak. The liability of the manufacturer is not directly considered. Questions of compensation for the victims were handled separately by the Patient Compensation Council.

In the view of experts, various of the constituents of Dent-O-Sept were considered to have an antibacterial effect if used in sufficient concentrations, but in the concentrations used in Dent-O-Sept there was no evidence that they would be effective either as antiseptics or for purposes of conservation. No published data were found as to efficacy of the Dent-O-Sept constitutents when used for oral hygiene, except where glycerol was concerned. Glycerol (sometimes with lemon juice) was in use in the period 1960–1980 for this purpose, and Dent-O-Sept dated from this period. Later workers had however advised against the use of glycerol since it had an unfavourable effect on the oral mucosa and induced

dehydration. Recent literature had also concluded that in these situations a soft toothbrush was preferable to a tipped spatula and that various antiseptic and antimicrobial agents (other than those present in Dent-O-Sept) could be helpful in preventing oral colonization with bacteria and fungi.

In August 2003 a technical group had reported on a series of questions relative to the nature and quality of Dent-O-Sept and the manner in which it had been used in hospital care. The group found that the manufacturer had labelled the product as follows: "Disposable swab for oral hygiene. Antiseptic. Ready for use for oral hygiene." In the hospitals concerned, the product had been used in accordance with these statements except for the fact that at various locations a single swab had been used several times in a given patient, being kept in a glass of water between applications. This the group regarded as "unfortunate" though it was not clear that this practice had any causal link with the subsequent infections with *Ps. aeruginosa.* Laboratory studies carried out to determine whether the bacterial content of the product rose during the period of retention in water gave inconsistent results; all in all it did not seen that the repeated use of the product was responsible for the outbreak. It was also the case that in many of the centres concerned a toothbrush had also been used, and the application of Dent-O-Sept was purely a supplementary measure.

Dent-O-Sept had not been produced under sterile conditions, and an aqueous product of this type without antiseptic effect can suffer subsequent contamination. The manufacturer did not supply information with the product indicating what precautions would be necessary to prevent contamination, nor was an expiry date given. The use of a CE symbol on medicinal appliances was rendered obligatory in June 1998. The manufacturer of Dent-O-Sept had thereafter improperly imprinted a CE symbol on the packages despite the fact that Dent-O-Sept did not meet the technical standards for such products set for the entire the European Economic Area. These standards would have demanded more adequate labelling, as well as documentation of the antiseptic and preservative effects of the components. On some occasions the manufacturer had observed that certain packages were returned from hospitals because they were not fully sealed or discolouration was present but, contrary to the regulations, the health authorities had not been notified of this fact. It had to be admitted, however, that the National Inspectorate of Public Health *(Helsetilsynet)* was not at the time in question equipped to deal systematically with such notifications.

As to *production standards*, the investigators pointed out that there would be no justification for introducing a general sterility requirement for hygienic products of this type exceeding the standards applicable to drugs used by this route (e.g. those acting on the upper respiratory system); sterile materials would however be required for certain high risk cases. An exception would apply to patients undergoing marrow transplantation, in whom exceptional steps have to be taken to eliminate every risk of infection. In general, however, Dent-O-Sept could well be regarded as a product analogous to those other medical devices which would normally be brought into contact with the mucosae but without penetration (e.g. bronchoscopes, cystoscopes). It is customary to sterilize such devices but not absolutely necessary, provided local disinfection is ensured.

In the overall assessment, the report concludes that the cause of the *Pseudomonas aeruginosa* outbreak was indeed the use of infected swabs of the Dent-O-Sept brand. The swabs had been infected during the manufacturing process, and the *manufacturer* had not labelled the product in accordance with the regulations. The *central health authorities* could not be held liable since the acquisition and use of products of this type was entirely delegated to the individual *health institutions* concerned. The latter had not been guilty of such gross negligence as to raise an issue of criminal liability, though they had been insufficiently aware of the best practices applicable to oral hygiene, especially in seriously ill patients. It was also clear that in the procurement and use of this product not all had adhered to the best standards, though they could not reasonably have known that the CE symbol in the label was in this

case misleading. A new and stricter regime for the selection and purchase of medicinal appliances was proposed as well as improved inspection to ensure that this regime is respected.

Commentary: This complex case is dealt with only in part in the report in question, which limits itself to the responsibility borne by the health institutions and authorities for the tragic events concerned. It is clear that there were faults at all levels, and the Inspectorate calls for changes in both the regulatory regime concerned and practice in the field. There are many such situations in medicine in which patient safety is dependent upon good training and sound common sense and cannot be guaranteed by law and regulation alone; the number of medical devices, materials and nursing aids in use is legion, and they are rarely regulated as strictly as are medicines. In this instance it would seem that an outdated hygienic practice had been allowed to persist over the years, despite the fact that it involved the use of a product which if properly evaluated would have probably been condemned. However, the very act of swabbing the mouth in seriously ill patients readily creates the impression that due care is being taken; the nurses responsible for the use of a particular type of branded swab purchased by the hospital will have no reason to question its safety, the physicians will be barely aware of the details of such nursing practice, the hospital pharmacy is unlikely to be involved, and a procurement department may continue for a long time to purchase a product apparently hallowed by long-term use. Add to this the fact that any or all parties had been misled by the label, suggesting that the product adhered to European standards, and one has a recipe for disaster. One would only add that the report seems to be very generous in exonerating the central health authorities, who at the very least could have taken steps to ensure that the CE symbol, which had been introduced in this field several years prior to the outbreak, was not improperly used on medical and nursing aids.