ESTIMATION OF EXPOSURE FROM SPILLED GLUTARALDEHYDE SOLUTIONS IN A HOSPITAL SETTING

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Abstract: Glutaraldehyde is commonly used in hospitals for cold disinfection of instruments which may be damaged by autoclaving. The increased use of automatic washer/disinfection machines has resulted in a greater risk of spills than with manual methods. A series of experiments was conducted to answer two related research questions: what was the likely range of airborne concentrations when glutaraldehyde is spilled, and are commonly used personal protective equipment ensembles effective and practicable in use? Objective measurements using three sampling methods (two pumped methods based on OSHA 64, one using treated filters and the other based on adsorbent tubes, and a Glutaraldemeter direct reading instrument) were conducted with spills of various surface areas of both 2 and 50% solutions of glutaraldehyde. Results ranged between <0.01 and 1.4 ppm. Two personal protective equipment ensembles were tested. One was based on a half-facepiece respirator with gas-tight goggles, while the other comprised a full-facepiece cartridge respirator. Both ensembles gave adequate protection against irritation, although in use the half-facepiece respirator and goggles tended to interfere with each other. The direct reading instrument generally underestimated the glutaraldehyde concentrations, although there was a significant association with the results obtained using the method based on adsorbent tubes. © 1997 British Occupational Hygiene Society. Published by Elsevier Science Ltd.

INTRODUCTION

Glutaraldehyde is commonly used in hospitals as a 2% 'activated' solution bearing trade names such as Cidex and Asep. The activation process involves adding an alkaline buffer, to optimise the solution's antimicrobial properties by raising the pH to between 7 and 8, immediately prior to use. These solutions are mostly used for cold disinfection of medical instruments such as endoscopes, which may be damaged by autoclaving, and for those which can tolerate high temperatures and pressures but which cannot be spared for the time it takes to be treated by hospital central sterilisation services.

At present, in the U.K., glutaraldehyde is assigned an Occupational Exposure Standard (OES) of 0.2 ppm averaged over 15 min (HSE, 1996). The critical health effects which this limit is designed to protect are skin, eye and respiratory tract irritation (HSE, 1993). It is, however, acknowledged that control to the present OES does not prevent symptoms of irritation in everyone who is exposed (HSE, 1995). Glutaraldehyde is also implicated in causing asthma (Gannon et al., 1995) and allergic contact dermatitis (Jordan et al., 1972).

In the past, glutaraldehyde has been used in basins or troughs to treat instruments which are then rinsed by hand. Increasing use of automatic and semi-automatic washer/disinfection machines, although reducing the potential for
exposure to vapour, ironically has resulted, in our experience, in a greater incidence of reported spills when compared with the manual methods. Glutaraldehyde has tended to degrade the plastic tubing used inside the machines in use in our hospitals, resulting in leaks. Also, in our opinion, staff using manual methods are aware of the risk of spills and appear to treat tasks involving glutaraldehyde with care. It is however, also likely that spills from manual disinfection methods will comprise a smaller volume which staff may not consider serious (a typical automatic washer contains 25 l per bath while a basin or trough holds approximately 5 l), and therefore spills may be under-reported.

A control strategy is required to deal with the increasing incidence of spills of glutaraldehyde. Any strategy will inevitably place great reliance on the use of personal protective equipment (PPE), particularly respiratory protection, to restrict workers' exposure. We have, therefore, carried out a series of experiments to determine the range of airborne concentrations which may be generated when glutaraldehyde is spilled and provide a qualitative assessment of the suitability of two different PPE ensembles.

MATERIALS AND METHODS

The work was carried out in the preparation room of a day surgery unit. The room, which measured approximately 3x3 m and was approximately 2.5 m high, had two doors; one leading onto a corridor, the other into the operating room. The room was routinely used for disinfection of flexible cytoscopes and was fitted with an automatic washer/disinfector (AFOS ICU2 type). The room did not have any mechanical ventilation and relied on air flow between the operating room and the corridor to provide general ventilation.

The experimental work was carried out at weekends when the unit was not being used for patients. This meant that staff were not subjected to potentially uncontrolled conditions when glutaraldehyde was spilled. The work was therefore carried out by the authors who undertook all tasks, to a protocol which was designed to minimise risk.

During the experiments the automatic washer unit was drained of glutaraldehyde and the doors to the room were sealed with a double layer of polythene sheeting to create a barrier whilst permitting access. Smoke tracers were used to locate the optimum position for a fan, used to create air movement within the room, to minimise turbulent air around the sampling area. A hot-wire anemometer was also used to confirm consistent air flow directly above the 'spilled' liquid.

Since thermal conditions were outwith the control of the experimenters, detailed measurements were taken continually during the experiments using a datalogging Tecora TCR Thermal Comfort Analyser. The temperature of the glutaraldehyde liquid was also measured at 60 s intervals during each experiment.

Objective measurements, which included both personal and static samples, were taken over 15 min periods using three sampling methods: the OSHA64 Treated Filter Method (OSHA, 1985), a variation of this method using treated silica gel adsorbent tubes (NIOSH 2532) (NIOSH, 1994)) and a hand-held direct reading instrument (Lion Glutaraldemeter (model: VER. 7/91-1)).
The 25 mm diameter filters were impregnated with 2,4-dinitrophenylhydrazine (DNPH) before being used. Filters were mounted in 7-hole sampling heads through which air was drawn, using battery operated pumps, at around 1 l/min. Personal samplers were mounted within 200 mm of the nose and mouth. Static samplers were placed so that the face of the sampling heads was vertical. Each sampling period lasted 15 min. Following sampling each filter was carefully removed from its sampling head, placed in individual, labelled storage tins before being returned to the laboratory for analysis by high performance liquid chromatography (HPLC).

The adsorbent tubes contained silica gel which had also been treated with DNPH (SKC Tube No. 226119). Air samples were obtained using battery operated pumps accurately calibrated at approximately 100 ml/min. Personal samplers were mounted in a similar manner to the treated filters, on the opposite lapel and static samplers were located beside the treated filters. The sampling period and analysis were also 15 min and HPLC respectively.

The Glutaraldemeter was calibrated at the start of each session using a pre-prepared calibration standard provided by the manufacturers. During sampling the instrument button was depressed but the reading was not taken until the display had stopped rising. This stabilisation tended to take at least 30 s. Readings were taken every 60 s during the same timed 15 min periods that the pumped samples were obtained.

The authors acted as volunteers for the experiments. Written consent was therefore not obtained. Two PPE ensembles were used to protect the experimenters. One was based on a half-facepiece respirator with gas-tight goggles (3M 4275 respirator and ARCO Eyeguard EG230 goggles). This combination was selected after several products were subjectively rated by one of the authors (KJMN) for comfort, fit and degree of interference with each other. The other ensemble was a full-facepiece cartridge respirator (3M 7900S with two 7161 A2 gas/vapour cartridges). Volunteers participating in the experiments were all aware of how to wear the devices and subjectively test their fit according to the written manufacturers' instructions accompanying the equipment.

Five experiments were designed, representing varying degrees of severity of floor spills (Table 1). Two sizes of aluminium tray were used to contain the glutaraldehyde. One ('small tray') measured approximately 0.125 m² and the other ('large tray') was about 0.25 m². A final experiment was undertaken where polythene sheeting was used to enable a self-contained surface area of approximately 2 m² to be created ('whole floor'). Experiments were conducted with both 2% activated (the type normally used in the workplace) and 50% non-activated solutions of glutaraldehyde. Two of the experiments were repeated to investigate the reproducibility of the measurements.

Table 1. Surface areas and concentrations of glutaraldehyde used

<table>
<thead>
<tr>
<th>Approximate surface area</th>
<th>Concentration of glutaraldehyde</th>
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<tbody>
<tr>
<td>Small tray (0.125 m²)</td>
<td>2% Activated</td>
</tr>
<tr>
<td>Large tray (0.25 m²)</td>
<td>2% Activated</td>
</tr>
<tr>
<td>Large tray (0.25 m²)</td>
<td>50%</td>
</tr>
<tr>
<td>Small and Large trays (0.375 m²)</td>
<td>50%</td>
</tr>
<tr>
<td>Whole floor (2 m²)</td>
<td>50%</td>
</tr>
</tbody>
</table>
For each experiment one of the authors 'spilled' an amount of glutaraldehyde into an appropriate container, sufficient to cover the surface to a depth of approximately 5 mm (enough to prevent any of the surface area drying out during the experiment). A pumped personal and static sample, using both monitoring methods, was obtained over the following 15 min period. The static monitor was located approximately 1 m above the liquid surface on a convenient flat, stable surface. Glutaraldemeter readings, spilled liquid temperature and subjective impressions of eye and upper respiratory tract irritation were recorded every 60 s.

At the end of each experiment the glutaraldehyde was discarded and the trays rinsed thoroughly. Any absorbent material used to dry contaminated surfaces was discarded into labelled polythene bags which were then sealed and removed from the room. Air was evacuated by connecting the fan to ducting leading outside the building. Measurements were made with the direct reading instrument until the glutaraldehyde concentration in the room returned to normal (i.e. <0.02 ppm, as measured with the Glutaraldemeter).

The statistical significance of differences between tube (NIOSH 2532) and filter (OSHA 64) sample concentration measurements was tested using a paired-sample $t$-test with log-transformed data. The transformation was undertaken because we assume that data of this type are likely to be log-normally distributed (Rappaport, 1991). Differences between the concentrations measured with personal and static samplers was tested in the same way. Linear regression of the log-transformed Glutaraldemeter readings and the filter sample concentrations was also undertaken.

RESULTS AND DISCUSSION

The results are shown in Table 2. Measured concentrations ranged from 0.01 ppm for a NIOSH 2532 sample for the small tray with 2% activated glutaraldehyde to 1.4 ppm for an OSHA 64 static sample with the large tray and 50% glutaraldehyde.

The average corrected effective temperature (CET) varied between 27.4°C (experiments 1, 3 and 4) and 24.0°C (experiments 2, 5–7) on the two survey days. The liquid temperature cooled by between 0.3 and 1.5°C during each experiment, confirming that evaporation was taking place.

Figure 1 shows the data obtained from the static samples plotted against that obtained for the personal samples. In general the static sample results were equal to or higher than the personal measurements. This is to be expected since the static samples were generally closer to the vapour source and this increases our confidence in the results. However, the difference between the personal and static measurements was not statistically significant ($p > 0.05$).

The arithmetic mean of the personal and static sample concentrations obtained using the various sampling methods are plotted against the area of glutaraldehyde 'spilled' in Fig. 2. While the samples obtained using both OSHA 64 and NIOSH 2532 seem in reasonable agreement, the Glutaraldemeter readings were consistently low, never exceeding the OES although the results from the other methods generally exceed it. Measured concentrations for all three sampling methods increased steadily
<table>
<thead>
<tr>
<th>Experiment</th>
<th>Personal samples</th>
<th>Static samples</th>
<th>Glutaraldemeter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OSHA 64</td>
<td>NIOSH 2532</td>
<td>OSHA 64</td>
</tr>
<tr>
<td>1. Small tray, 2% activated glutaraldehyde</td>
<td>0.06</td>
<td>0.02</td>
<td>0.03</td>
</tr>
<tr>
<td>2. Small tray, 2% activated glutaraldehyde</td>
<td>0.01</td>
<td>0.07</td>
<td>0.01</td>
</tr>
<tr>
<td>3. Large tray, 2% activated glutaraldehyde</td>
<td>0.57</td>
<td>0.11</td>
<td>0.53</td>
</tr>
<tr>
<td>4. Large tray, 50% glutaraldehyde</td>
<td>0.78</td>
<td>0.24</td>
<td>0.87</td>
</tr>
<tr>
<td>5. Large tray, 50% glutaraldehyde</td>
<td>0.31</td>
<td>0.33</td>
<td>0.63</td>
</tr>
<tr>
<td>6. Small and large trays, 50% glutaraldehyde</td>
<td>0.78</td>
<td>0.78</td>
<td>0.78</td>
</tr>
<tr>
<td>7. Whole floor, 50% glutaraldehyde</td>
<td>0.18</td>
<td>0.03</td>
<td>0.35</td>
</tr>
</tbody>
</table>
with increasing surface area of 'spilled' liquid and the concentration of glutaraldehyde, with the exception of the experiment involving the whole floor. Reasons for this are unclear.

When the personal measurements obtained for the NIOSH 2532 method were plotted against the corresponding data for the OSHA 64 samples there was no significant correlation between the results (Fig. 3). Although the results appear similar there is a great deal of random scatter. The statistical analysis showed that the differences were not significant at the 5% level.
The only combination to produce a significant association was the log of the OSHA 64 results with the log of the Glutaraldemeter readings ($p = 0.011$). The regression equation is:

$$F = 34.6G^{2.1}$$

where $G$ is the Glutaraldemeter reading and $F$ the estimated filter concentration. This implies that the Glutaraldemeter was performing with a systematic error. The instrument had been regularly serviced and was always carefully calibrated according to manufacturers instructions using a current glutaraldehyde standard. However, its performance had always given the authors cause for concern. It had been returned to the manufacturer on a number of occasions when the readings it gave did not match with symptoms of irritation experienced by users and others present when readings were taken (e.g. a strong smell of glutaraldehyde but a very low concentration indicated by the glutaraldementer or no detectible odour with a reading in the region of the OES). Discussions with other users of Glutaraldemeters has revealed similar difficulties.

The results also indicate difficulties with the pumped sampling methods for glutaraldehyde and their lack of full validation. On the basis of the present data it was concluded that the OSHA64 method gave results with acceptable accuracy and precision and its use was therefore adopted for future surveys. A modification of the OSHA 64 method has recently been published (Cuthbert and Groves, 1995) and it is intended to investigate its use. Use of the Glutaraldemeter will be continued using the correction factor given above to take account of the apparent non-linear nature of its readings in relation to other measurement methods.

Previous published work (Scobbie and Groves, 1995) suggested that up to 2 ppm of vapour could be generated above 2% activated glutaraldehyde solutions. This suggests that the highest concentration, in the event of a large spill, is likely to be approximately 10 times the OES. The highest result obtained during our
experiments was 1.43 ppm which is in good agreement with Scobbie and Groves and leads us to conclude that any chosen respiratory protective device must have, in practice, at least an effective protection factor of 10. The quoted information from the manufacturers indicated that either of the chosen ensembles could be suitable on this basis although additional factors, such as the compatibility of different items of PPE, must be taken into account. Our experience during these experiments indicated that either PPE ensemble was capable of eliminating eye and respiratory irritation from the ‘spilled’ glutaraldehyde.

It is our opinion that the full-facepiece device is preferable since in practice the half-mask/goggle combination was found to be awkward to fit and the two components tended to interfere with each other during use. The full-facepiece device could be overtightened at the straps on top of the head resulting in significant leakage but it was felt that this problem could be overcome with training. A spill response protocol was subsequently produced, in conjunction with staff, and introduced with training for all staff likely to need to deal with spills. Use of the half-mask/goggle ensemble was retained for routine tasks involving mixing and disposing of glutaraldehyde-containing solutions. Feedback from staff using the equipment has been positive.

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