J. Hyg., Camb. (1983), **90**, 241–252
Printed in Great Britain

Contaminated first-aid dressings: Report of a Working Party of the PHLS

COMPILED BY R. R. MARPLES

Secretary to the Working Party, Division of Hospital Infection, Central Public Health Laboratory, Colindale Avenue, London NW9 5HT*

(*Received* 19 *November* 1982; *accepted* 22 *November* 1982)

SUMMARY

In a collaborative study 12 Public Health Laboratory Service laboratories and the Division of Hospital Infection, Central Public Health Laboratory, investigated the degree of contamination of standard dressings produced by manufacturers in India or in England by a comparison of the results of culture of 25 sterilized dressings with those of 25 untreated dressings. Of the 38 batches of dressings made in India 27 (71 %) were judged contaminated and another six could be so judged when *Bacillus* species were examined. In two batches laboratory contamination precluded a judgement and only three batches passed the test. Of the 27 batches made in England, only three gave any evidence of contamination at the lowest level of significance. Repeat investigation of one of these batches gave no evience of contamination.

Organisms of the genus *Bacillus* and fungi were associated with contamination; micrococci and propionibacteria were laboratory contaminants. There was evidence for both failure of sterilization and of contamination after sterilization during the manufacture of dressings.

INTRODUCTION

In November 1981, some imported dressings intended for first-aid use were found to be contaminated (Thomas, Dawes & Hay, 1981). As very large numbers of these dressings were known to be distributed in first-aid kits throughout the country, the Department of Health issued Hazard Warning Notices, and the Chief Medical Officer, with the agreement of the Secretary of State for Social Services, asked the

* *Members of the Public Health Laboratory Service (PHLS) Working Party:* Dr P. D. Meers (Chairman), Deputy Director of the PHLS, London; Dr B. W. Barton, Director, PHLS, Sheffield; Dr C. Dulake, Director, PHLS, Dulwich, London; Dr G. L. Gibson, Director, PHLS, Leeds; Dr R. J. C. Hart, Director, PHLS, Exeter; Dr W. L. Hooper, Director, PHLS, Poole; Dr A. E. Jephcott, Director, PHLS, Bristol; Dr M. J. Lewis, Director, PHLS, Nottingham; Mr C. Mackintosh, Senior Microbiologist, Division of Hospital Infection (DHI), Central Public Health Laboratory (CPHL), London; Dr P. G. Mann, Director, PHLS, Bath; Dr C. A. Morris, Director, PHLS, Shrewsbury; Dr S. W. B. Newsom, Consultant Microbiologist, Addenbrooke's Hospital, Cambridge; Dr G. C. Turner, Director, PHLS, Liverpool; Dr A. T. Willis, Director, PHLS, Luton; Dr R. R. Marples (Secretary), Deputy Director, DHI, CPHL, Colindale; Mr R. T. Rogers (Observer), Deputy Director, Scientific & Technical Branch, Department of Health & Social Security.

Director, Public Health Laboratory Service (PHLS) to conduct an enquiry, and make recommendations.

A Working Party was set up to study the degree of contamination of Standard Dressings (The Pharmaceutical Codex, 1979). Twelve PHLS laboratories participated with the Division of Hospital Infection (DHI), Central Public Health Laboratory (CPHL), Colindale, co-ordinating their activities and independently carrying out additional studies.

The Working Party's discussions took place in the knowledge that preliminary studies had indicated a contamination rate of about two-thirds in the suspect dressings. Difficulties in carrying out tests were also recognized from reports of initially high levels of accidental laboratory contamination (Thomas, Dawes & Hay, 1981, Anon, 1982). The procedure finally adopted was to culture whole dressings in a single medium, thioglycollate broth. This method was chosen so as to detect significant pathogens rather than to follow strictly the procedure recommended by the British Pharmacopoeia (1980) or the European Pharmacopoeia Commission (1971). The test compared the results of the culture of batches of dressings, tested individually, with the results of control dressings from the same batch which had previously been sterilized by an exceptionally high dose (7·5 megarads) of gamma radiation to provide information on the level of laboratory contamination. Additional studies were carried out by DHI to validate the chosen procedure and to determine, where possible, the level and source of contamination. Studies were confined to standard non-adhesive dressings (BPC numbers 7, 8, 9, 10, 11, 12 and 16; The Pharmaceutical Codex, 1979) from Indian and British sources.

MATERIALS AND METHODS

Source of dressings

The main collection of dressings was undertaken by the Supplies Division of the Department of Health and Social Security (DHSS) from several suppliers who imported and applied an outer package to dressings originally manufactured and sterilized in India and also dressings from three British manufacturers. The collection was supplemented with dressings collected by the PHLS. The dressings were delivered to DHI for the preparation of test batches. The dressings are double wrapped, but the outer surface of the inner wrap may not be sterile.

Preparation of test batches

Wherever possible each batch consisted of 100 dressings of the same type from the same source. The dressings in each batch were numbered consecutively from 1 to 100 and from among the first 50, 25 were selected at random and sterilized by exposure to 7·5 megarads of gamma rays (Irradiated Products, Swindon), an exposure sufficient to ensure sterility under the conditions of the test (Silverman & Sinskey, 1977). From some batches 25 dressings were similarly irradiated from the second 50, for more detailed study at DHI. Each test batch thus consisted of 25 irradiated control dressings and 25 non-irradiated test dressings, except for one batch where only 22 dressings were irradiated. Where possible, duplicate batches were prepared. The testing laboratories did not know which dressings had been irradiated.

Distribution of dressings and media

All laboratories were supplied with dehydrated thioglycollate medium USP of the same batch (Oxoid Ltd) and five batches of 50 dressings, at least one of which was of British manufacture. Standard forms for recording results were provided.

Identification of organisms

Laboratories were asked to identify the organisms found by their usual techniques, that is those suitable for organisms of medical significance. In addition, the Luton Public Health Laboratory studied isolates of anaerobic bacteria and the Food Hygiene Laboratory, CPHL, identified aerobic spore-forming bacilli (ASB). Some isolates of staphylococci were studied at DHI.

RESULTS

From the collection of dressings, it was possible to prepare 38 batches of dressings of Indian manufacture and 27 batches of British manufacture. The results of the simple sterility tests on each batch and of the main groups of organisms recovered are listed in Tables 1 and 2 for both the irradiated and the non-irradiated dressings. The statistical tests were of a comparison of the number of positive results in the non-irradiated dressings with those in the irradiated dressings either by χ^2 or by exact probability methods.

Sterility tests

The number of dressings yielding growth of any sort in the non-irradiated half of the batch was significantly greater than the number of dressings yielding growth of any sort in the irradiated control series in 27 (71 %) of the 38 batches of Indian manufacture. Laboratory contamination appeared to preclude detection of statistically significant intrinsic contamination in a further six batches, no conclusion could be drawn for two batches and only three batches could be accepted as passing the test. Overall, positive cultures were obtained from 31·2 % of the irradiated controls and from 73·3 % of the non-irradiated dressings.

In contrast, in only three of the 27 batches of dressings from British manufacturers did the 'test' samples show a difference from the irradiated controls. In each case the difference was of borderline significance. One of these batches (Batch 40) was also tested at another laboratory where no evidence of contamination was found. Overall, positive cultures were obtained from 21·2 % of the irradiated dressings and 23·4 % of the non-irradiated dressings. The difference between the total number of positives in the irradiated batches, 143 positive of 674 tested, and the number in the non-irradiated batches, 157 positive of 671 tested, could be interpreted as a measure of the effect of a sterile outer surface of the inner wrapping in the irradiated dressings and the non-sterile surface of the non-irradiated dressings. If this interpretation is valid the magnitude of the difference gives no support for the hypothesis of gross contamination of the dressings from the wrappings nor for the hypothesis that the level of radiation produced significant toxic products (Dadd *et al.* 1970).

https://doi.org/10.1017/S0022172400028916 Published online by Cambridge University Press

Table 1. *Dressings of Indian manufacture*

	Number of dressings yielding growth of														
	Any organism			ASB			Fungi			Micrococci			Anaerobes		
	γ†	Non‡	Sig.§	γ	Non	Sig.	γ	Non	Sig.	γ	Non	Sig.	γ	Non	Sig
1	9	13	N.S.	0	8	**	0	0	N.S.	2	1	N.S.	7	5	N.S.
1	0	19	**	0	6	*	0	13	**	0	1	N.S.			
2	2	12	**	0	9	**	0	1	N.S.	2	0	N.S.			
3	20	14	N.S.	0	6	*	0	0	N.S.	7	2	N.S.	15	5	**
4	2	3	N.S.	1	3	N.S.	0	0	N.S.	1	1	N.S.			
5	1	22	**	0	6	*	0	17	**	1	0	N.S.			
6	16	22	N.S.	0	8	**	0	10	**	14	8	N.S.	3	2	N.S.
7	5	21/24	**	0	10	**	0	10	**	3	3	N.S.			
7	1	21	**	0	14	**	1	10	**	0	1	N.S.			
8	1	16	**	1	9	**	0	7	**	0	0	N.S.			
9	8/23	7/25	N.S.	0	0	N.S.	0	0	N.S.	6	4	N.S.			
10	1	20	**	1	13	**	0	11	**	0	0	N.S.			
11	17	25	**	1	25	**	1	0	N.S.	16	0	**			
12	18	24	*	0	15	**	0	0	N.S.	6	9	N.S.			
13	1	16	**	0	15	**	0	1	N.S.	1	0	N.S.	0	2	N.S.
14	11/20	17/25	N.S.	5	15	**	0	0	N.S.	6	3	N.S.			
14	7	23	**	0	21	**	0	1	N.S.	5	4	N.S.			
15	5	21	**	2	21	**	0	0	N.S.	3	0	N.S.			
16	12	25	**	1	18	**	5	13	*	6	6	N.S.			
17	3	24	**	0	11	**	1	14	**	2	0	N.S.			
18	12	19	N.S.	1	15	**	3	1	N.S.	10	5	N.S.	0	2	N.S.
19	12	24	**	2	14	**	0	1	N.S.	9	7	N.S.	0	1	N.S.
19	4	16	**	2	12	**	0	2	N.S.	4	1	N.S.			
19	6	24	**	0	7	**	4	1	N.S.	1	1	N.S.			
20	8/22	27/28	**	0	8	**	7	26/28	**	1	0	N.S.			
21	19	24	*	0	15	**	2	2	N.S.	13	5	**			
22	2	12	**	0	5	*	0	4	N.S.	2	5	N.S.			
23	16/20	23/23	*	0	7	**	0	4	N.S.	11	9	N.S.	0	1	N.S.
24	3	12	*	0	7	**	0	1	N.S.	3	5	N.S.			
24	5	17	**	0	6	**	2	9	**	3	4	N.S.	2	1	N.S.
24	0	19	**	0	7	**	0	13	**	0	0	N.S.			
25	6	15	*	0	9	**	0	4	N.S.	6	2	N.S.			
26	13	25	**	1	22	**	10	3	*	2	0	N.S.	0	3	N.S.
27	0/24	23	**	0	21	**	0	4	N.S.	0	0	N.S.	0	9	**
28	1	4	N.S.	0	4	N.S.	1	0	N.S.	0	0	N.S.			
29	23/24	23/24	N.S.	1	13	**	0	0	N.S.	13	7	N.S.			
30	15	18	N.S.	6	12	N.S.	7	2	N.S.	6	1	*			
31	2	4	N.S.	0	1	N.S.	0	0	N.S.	1	1	N.S.	1	2	N.S.

† Gamma-irradiated dressings.

‡ Non-irradiated dressings.

§ Statistical significance, where N.S. = non-significant, * denotes $P < 0{\cdot}05$ and ** denotes $P < 0{\cdot}01$. The denominator was 25 except where stated and for batches studied in more than one laboratory all results are given.

https://doi.org/10.1017/S0022172400028916 Published online by Cambridge University Press

Table 2: *Dressings of British manufacture*

	Number of dressings yielding growth of														
	Any organism			ASB			Fungi			Micrococci			Anaerobes		
	γ†	Non‡	Sig.§	γ	Non	Sig.	γ	Non	Sig.	γ	Non	Sig.	γ	Non	Sig.
32	2	1	N.S.	0	0	N.S.	0	0	N.S.	0	0	N.S.	1	1	N.S.
33	0	1/24	N.S.	0	0	N.S.	0	0	N.S.	0	1	N.S.			
34	3	2	N.S.	0	0	N.S.	0	0	N.S.	0	1	N.S.	2	1	N.S.
34	4	3	N.S.	2	2	N.S.	0	0	N.S.	1	1	N.S.			
35	3	1	N.S.	1	0	N.S.	0	0	N.S.	2	1	N.S.			
36	1	6	*	0	1	N.S.	0	0	N.S.	1	5	N.S.			
37	10	13	N.S.	0	0	N.S.	0	1	N.S.	8	9	N.S.			
38	2	2	N.S.	2	1	N.S.	0	0	N.S.	0	1	N.S.			
39	6	5	N.S.	0	0	N.S.	0	1	N.S.	6	3	N.S.			
40	1	6	*	0	1	N.S.	0	0	N.S.	1	3	N.S.	0	1	N.S.
40	2/24	1/23	N.S.	0	0	N.S.	0	0	N.S.	2	1	N.S.			
41	0	1	N.S.	0	0	N.S.	0	0	N.S.	0	1	N.S.			
42	2	3	N.S.	0	1	N.S.	0	0	N.S.	2	1	N.S.			
43	14	16	N.S.	0	1	N.S.	0	0	N.S.	6	10	N.S.			
44	0	3/24	N.S.	0	2	N.S.	0	0	N.S.	0	1	N.S.			
45	3	2	N.S.	0	0	N.S.	0	0	N.S.	3	2	N.S.			
46	15	18	N.S.	2	3	N.S.	0	0	N.S.	12	16	N.S.			
47	3	1	N.S.	0	1	N.S.	0	0	N.S.	2	0	N.S.			
48	11	5	N.S.	0	0	N.S.	0	0	N.S.	5	1	N.S.	6	5	N.S.
49	18	18	N.S.	1	2	N.S.	2	1	N.S.	18	17	N.S.			
50	3	7	N.S.	0	3	N.S.	1	0	N.S.	2	3	N.S.			
51	2	1	N.S.	0	0	N.S.	0	0	N.S.	2	1	N.S.			
52	0	0	N.S.	0	0	N.S.	0	0	N.S.	0	0	N.S.			
53	0	1	N.S.	0	1	N.S.	0	0	N.S.	0	0	N.S.			
54	17	17	N.S.	2	1	N.S.	2	0	N.S.	11	13	N.S.			
55	18	12	N.S.	2	1	N.S.	1	0	N.S.	11	8	N.S.			
56	3	11	*	0	0	N.S.	0	0	N.S.	3	10	*			

Abbreviations and Symbols as Table 1.

Organisms recovered

Four main groups of organisms were regularly isolated: aerobic spore-forming bacilli, fungi, micrococci and anaerobes including both clostridia and propionibacteria. There were occasional isolations of other organisms including aerobic diphtheroids, streptococci and coliforms. A typical result of a batch tested in two laboratories is shown in Table 3.

Aerobic spore-forming bacilli (ASB)

Recovery of ASB from non-irradiated dressings significantly exceeded recovery from irradiated dressings in 33 of the 38 batches of Indian manufacture but in none of the 27 batches of British manufacture as shown in Tables 1 and 2. A total of 503 isolates were identified, 454 from non-irradiated dressings of Indian manufacture and 49 from irradiated Indian dressings or from British dressings (irradiated or non-irradiated). This latter group was considered to represent laboratory contaminants.

https://doi.org/10.1017/S0022172400028916 Published online by Cambridge University Press

Table 3. *Example of a contaminated batch examined by two laboratories*

Irradiated		Not irradiated	
Dressing number	Result	Dressing number	Result
Laboratory 7			
601	Diphtheroid	604	Trial run
602	—	606	*Aspergillus*
603	—	607	*Aspergillus*
605	Diphtheroid	608	*B. pumilus*, *B. megaterium*
609	—	613	—
610	Coag. neg. staph.	618	*Aspergillus*, Coag. neg. staph.
611	—	620	*Aspergillus*
612	—	621	*B. sphaericus*, *B. licheniformis*
614	Coag. neg. staph.	622	*B. subtilis*
615	Coag. neg. staph.	624	*Aspergillus*
616	—	625	*Bacillus* sp.
617	—	628	*Aspergillus*
619	—	629	—
623	—	630	*B. licheniformis*, Coag. neg. staph.
626	—	632	*B. licheniformis*
627	—	633	*Aspergillus*
631	—	634	—
636	—	635	*Aspergillus*
637	—	639	*B. filicolonicus*
638	—	641	*Aspergillus*
640	—	643	*B. subtilis*, *B. circulans* complex
642	—	644	Coag. neg. staph.
645	—	647	*Aspergillus*
646	—	648	*B. megaterium*, *B. laterosporus*
649	—	650	*B. licheniformis*, *B. pumilus* *B. circulans* complex
Laboratory 13			
652	—	651	*B. licheniformis*, *B. subtilis*
656	—	653	*B. cereus* serotype 16
657	—	654	fungi
659	—	655	*B. subtilis/licheniformis*, *B. licheniformis*
660	—	658	*B. licheniformis*
661	—	662	*Bacillus* sp.
663	Fungi	664	Fungi
667	—	665	—
670	—	666	Fungi, *B. subtilis*
673	—	668	—
678	—	669	—
679	—	671	Fungi
680	—	672	Fungi
681	—	674	*B. subtilis*, *B. licheniformis*, *B. circulans* complex
682	—	675	Fungi
684	—	676	—
686	—	677	*B. subtilis*
688	—	683	Fungi
689	—	685	Fungi, *B. subtilis*, *B. licheniformis*
690	—	687	*B. brevis*
691	—	692	*B. subtilis*, *B. licheniformis*
693	—	694	*B. subtilis*
698	—	695	Coag. neg. staph, *B. lentus*, *B. licheniformis*
699	—	696	Fungi
700	—	697	*B. stearothermophilus*

https://doi.org/10.1017/S0022172400028916 Published online by Cambridge University Press

The most frequent species was *Bacillus cereus* identified 127 times, 126 from the non-irradiated Indian dressings, a significant association. Within this species 13 serotypes, including some provisional types, were found more than once, another 12 were found singly and 58 isolates were untypable. The frequency of serotypes did not resemble either the distribution of types implicated in food poisoning or those in wound infection. *B. subtilis* was isolated 94 times, 87 times from the non-irradiated Indian dressings, a frequency close to that expected from the proportion of all ASBs isolated from non-irradiated dressings. *B. licheniformis*, isolated 86 times, only 72 times from the non-irradiated dressings of Indian manufacture was significantly over-represented in the laboratory contamination group. The other frequently isolated species, *B. megaterium*, *B. pumilus* and *B. circulans* showed no association with either group of dressings while *B. sphaericus* and *B. firmus* were related to the Indian dressings at the borderline of significance. Eighteen other species were identified 10 or less times.

Batches clearly differed in ASB contamination. For example batch 11 yielded 10 serotypes of *B. cereus* while in other batches no *B. cereus* were recovered. No clear difference was shown between different Indian manufacturers.

The difference between the frequency of recovery of ASB from the dressings of Indian manufacture and from other dressings strongly suggest that the contamination was intrinsic to the Indian dressings and not due to laboratory contamination.

Fungi

Although the use of thioglycollate broth would not be recommended for the isolation of fungi, significant numbers of fungal contaminants were detected in 12 of the 38 batches of dressings of Indian manufacture but in none of the 27 batches of British manufacture. In one batch (26) a significant excess was found in the irradiated dressings as compared to the non-irradiated dressings. The latter were, however, heavily contaminated with the ASBs and it is possible that bacterial growth had suppressed that of the fungi. In every case fungal contamination was significant only in batches with significant contamination with ASB. Where identified the fungal contaminants were commonly *Aspergillus niger*, however, *Penicillium* species were also present.

Micrococcaceae

These organisms appeared to be laboratory contaminants being recovered, usually infrequently, from all but eight batches of the 65 tested. Significant differences in recovery were detected in four batches, three of Indian manufacture. In these three batches the excess was in the irradiated dressings, with heavy contamination by ASB in the non-irradiated dressings also detected. Overgrowth by ASB could account for the difference, as in the fungal results of batch 26. The single batch of British manufacture with an excess of cocci of borderline significance in the non-irradiated dressings may confidently be ascribed to chance.

Staphylococcus aureus

This organism was found in 25 cultures and appeared to be a laboratory contaminant as 19 of the 25 dressings were irradiated. On three occasions phage

Table 4. *Laboratory contamination rates (percentage of positive cultures from irradiated dressings)*

	Batch					
Laboratory	1	2	3	4	5	Total
1	4	8	36	44	8	20
2	4·17	0	55	12	14	15
3	80	12	20	24	0	27·2
4	8	48	12	12	60	28
5	4	12	4	8	12	8
6	40	64	48	72	20	48·8
7	20	8	0	0	0	5·6
8	4	24	48	68	72	43·2
9	33·3	4	16	8	12	14·6
10	4	0	24	12	0	8
11	8	68	36·4	52	60	44·8
12	76	56	76	64	95·8	73·5
13	16	8	0	4	32	12
Total	23·2	24	28·9	29·2	28·9	26·8

typing confirmed this assumption with indistinguishable strains found in two batches tested in the same laboratory.

Of the few coagulase-negative staphylococci and micrococci recovered the most frequent identifications were of *S. epidermidis*, and of pigmented strains similar to *S. hominis* and *Micrococcus luteus*.

Anaerobic organisms

Because of the initial reports and because of the potential risk from contamination with anaerobic spore-forming organisms of the genus *Clostridium*, the protocol included anaerobic subculture of all positive cultures at 7 and 14 days. The medium used had been shown to support growth from very small inocula of freshly isolated clostridia, but the presence of numerous aerobic contaminants may have reduced the recovery of anaerobes.

Clostridium species showed a significant excess recovery in the non-irradiated dressings in only one batch (27) which could be a chance finding but, overall, 19 non-irradiated dressings of Indian manufacture yielded clostridia while only one was recovered from the irradiated dressings. In the dressings of British manufacture two irradiated dressings and one non-irradiated dressing yielded clostridia which were not further identified.

From the dressings of Indian manufacture *Clostridium perfringens* was isolated six times, *C. sporogens* five times, *C. innocuum* four times, once from an irradiated dressing. Other identifications included *C. sordellii* (2), *C. beijerinckii* (2), *C. bifermentans* (2) and single isolates of *C. tertium*, *C. subterminale* and *C. fallax*. One isolate could not be identified. *Cl. tetani* and *Cl. botulinum* were not recovered from these dressings.

Propionibacteria were also recovered from 43 dressings but the distribution of isolations suggested laboratory contamination. In only one batch was a significant deviation detected and this was an excess in the irradiated dressings in the presence of a low but significant level of true ASB contamination.

Laboratory contamination

Contamination of the dressings in the laboratory was expected because of the difficulties of handling the packaging and because of the complex structure of some of the dressings. The design of the study was such that a laboratory contamination rate of 25% could be distinguished from a true contamination rate of 66%. The number of positive cultures from the irradiated dressings irrespective of their country of origin form a measure of laboratory contamination (Table 4). Of the 13 laboratories seven returned better results than allowed for, two were close to the contamination level expected but four laboratories returned laboratory contamination rates of greater than 40% over the five batches tested. Confirmation of laboratory contamination could be demonstrated for three of these laboratories in the isolations of indistinguishable strains of *S. aureus* from separate batches, of α-haemolytic streptococci and indistinguishable strains of coagulase-negative staphylococci from more than one batch of dressings.

The laboratories were asked to describe the procedure and circumstances of testing in detail. It was not possible to assess the effects of all the factors that could affect laboratory contamination but a major factor in preventing poor results appeared to be the use of clean air cabinets to protect the work from laboratory contamination. Of the 25 batches of dressings tested in cabinets, only six showed a laboratory contamination rate of more than 20% while 24 of 40 batches cultured without clean air cabinets showed laboratory contamination rates of more than 20%. Other variations in technique appeared to be less important.

Additional studies

Validation of the sterility test

The five batches of dressings for sterility testing in the DHI were tested with a modified protocol. All procedures of opening and culturing the dressings were carried out in accordance with a standard protocol in horizontal laminar-flow clean air cabinets (Envair (UK) Ltd.). Each dressing was cut in half after removal of the wrappings and cultured in thioglycollate broth and in trypticase soy broth. In three batches of contaminated dressings cultured in this way, both cultures were positive in 33, both negative in 14, nine were positive in the thioglycollate culture alone and 19 were positive in the trypticase soy broth alone. The comparable figures for the two non-contaminated batches were; both positive, 1: thioglycollate positive, 2 and trypticase positive 7. These results suggest that little precision was lost as a consequence of the decision to culture in only a single medium, thioglycollate broth. The rather high frequency of one medium being positive and the other negative would suggest a relatively low level of contamination within each individual dressing.

Tests on the randomization procedure

The numbers of the dressings chosen for irradiation were tested in four ways for randomization. First, any particular number should have been equally represented in the irradiated and non-irradiated sub-batches of the 65 groups tested. The frequency found matched that predicted from chance ($\chi^2 = 2{\cdot}99$; 5 D.F. $0{\cdot}75 > P > 0{\cdot}5$). Low numbers and high numbers should have appeared in each at equal frequencies. Over five classes no bias was detected ($\chi^2 = 1{\cdot}5$,

https://doi.org/10.1017/S0022172400028916 Published online by Cambridge University Press

4 D.F. $0{\cdot}97 > P > 0{\cdot}75$). Terminal numbers should have been equally represented. Examination of this showed an excess of numbers ending in 6 among the irradiated dressings but, overall, the bias was non-significant. Also approaching significance ($0{\cdot}1 > P > 0{\cdot}05$) was the frequency of runs of consecutive numbers among the irradiated dressings. Fewer runs were found than expected perhaps reflecting the increased mixing of those dressings that tended to stick together because of their packaging.

Dissection studies

Based on the results by the participating laboratories small numbers of contaminated dressings were chosen from grossly contaminated batches and studied in greater detail.

Each dressing was divided in half and one half was dissected into its component parts, i.e. the whole inner wrapping, the short outer bandage, the pad and the long bandage that formed the centre of the package. Each portion was agitated in buffered Triton X-100, a non-ionic detergent, and the wash fluid passed through a membrane filter which was finally placed on a nutrient agar surface for quantitative culture. The other half-dressing was similarly cultured.

Thirteen dressings from batch 12 were cultured in this way as heavy contamination with ASB had been reported in the first half of this batch. Only two of the 65 cultures were sterile and the counts ranged from 0 to 254 but the majority were relatively low. The median count from the whole inner wrapper was only three, the outer bandage five and from the pad and from the inner bandage three colonies. These figures suggest a low level of contamination distributed throughout the dressing. Correlation with the other half-dressing was poor. Similar results were obtained with batch 24.

Quantification of the contamination in batch 16 was more difficult because of the contamination with fungi. Semiquantitative estimates of the density of growth from 10 dissected dressings of this batch suggested very heavy contamination of the inner wrapper and diminishing contamination towards the centre of the package. Similar results, but with a lower level of contamination could be seen for batch 26. One batch of cotton wool was dissected into approximately equal-sized subsamples. The results again indicated ASB throughout, with high numbers on the inner wrapping and averages of 8, 13 and 12 for three equally sized pieces inwards into the roll.

Batch 57, not included in the main study, was of interest as it was the only batch from the manufacturers using licence number 1040. Fifteen dressings were dissected and four were positive for ASB at scattered depths in the packages.

DISCUSSION

The organization of the PHLS permitted the rapid formation of a collaborative group which first met on 22 January 1982, the speedy preparation of a standard protocol and collection of the test dressings, complete by 1 February. Batches of dressings were despatched on 5 February and 22 February and the final results were returned to DHI on 5 April. The draft report was considered on 13 May and the Whitehead report (1982) was tabled before the end of the month.

The primary question of the sterility of imported and home-produced standard first-aid dressings was clearly answered. Dressings of Indian manufacture were frequently contaminated with ASB (33 of the 38 batches tested). Although only one batch contained significant numbers of dressings contaminated by *Clostridium* species, the total results suggested a small but real level of clostridial contamination. Fungal contamination was also demonstrated in 12 batches although the protocol was not optimal for recovery of this group of organisms. Dressings of British manufacture showed no evidence of such contamination.

The design of the study defined each batch as 25 dressings sterilized by irradiation as controls to be tested with 25 non-irradiated dressings. This design allowed the rate of laboratory contamination to be assessed and hence of the significance of growth in the test batches. Growth of any sort was significantly more frequent in 27 of the 38 test batches of Indian manufacture and in three of the 27 test batches of British manufacture. The results were of borderline significance only in five of the Indian and all three of the British batches (in one of which a duplicate study did not confirm the contamination). Laboratory contamination appeared to be the main cause of recovery of staphylococci, streptococci and propionibacteria. The value of clean-air cabinets in reducing laboratory contamination was evident.

Although contamination of the dressings of Indian manufacture was frequent, the levels of contamination in each dressing were relatively low with median counts of ASB usually less than 10. The distribution of ASB within the dressings was compatible with a failure of sterilization. However, the fungal contamination was heaviest in the outer part of the dressings suggesting post-sterilization contamination. Visual evidence that the paper wrappings of some of the Indian dressings had at one time been wet suggests the likely mode of entry of this contamination.

The findings of this study indicated that most of the contaminating organisms were of low pathogenicity. Since first-aid dressings are frequently applied to wounds already contaminated the added risk to health of these low levels of contamination in the dressings must be small. Nevertheless, the risk is judged to be unacceptable, quite apart from the propriety of labelling such a product 'sterile' (Whitehead, 1982).

The members of the working party thank their staffs and particulary Mr P. Hoffman, of D.H.I., Mr J. Kramer and Mrs Pratima Rawal of Food Hygiene Laboratory and the staff of Luton PHL for their efforts. We thank PHLS central stores for assistance and DHSS for unstinting co-operation and financial support.

REFERENCES

Anonymous (1982). Investigation of first-aid dressings claimed to be sterile. Note by DHSS laid in the Library of the House of Commons, 26 January.

British Pharmacopoeia (1980). London: Her Majesty's Stationary Office. Appendix XVI, pp. A 186–190.

Dadd, A. H., Dagnall, V. P., Everall, P. H. & Jones, A. C. (1970). The survival of *Streptococcus pyogenes* on bacteriological swabs made from various fibres. *Journal of Medical Microbiology* **3**, 561–572.

European Pharmacopoeia (1971). Vol. II, pp. 53–57. Maisonneuve S.A. 57 Sainte Ruffine.

SILVERMAN, G. J., & SINSKEY, A. J. (1977). Sterilization by ionising radiation. In *Disinfection, Sterilization and Preservation*, 2nd ed. (ed. S. S. Black). Philadelphia: Lea & Febriger.

THE PHARMACEUTICAL CODEX (1979). 11th ed., pp. 896–897. London: Pharmaceutical Press.

THOMAS, S., DAWES, C. E. & HAY, N. P. (1981). Microbiological contamination of imported wound dressings. *Pharmaceutical Journal*, 19 December, p. 26.

WHITEHEAD, J. E. M. (1982). Report to the Secretary of State for Social Services on microbial contamination of non-adhesive 'sterile' first-aid dressings. Laid in the Library of the House of Commons, May.