SCOTTISH HOSPITALS INQUIRY

Bundle of documents for Oral hearings commencing from 19 August 2025 in relation to the Queen Elizabeth University Hospital and the Royal Hospital for Children, Glasgow

Bundle 44 – Volume 4

Reports by Dr Chaput and Dr Mumford, and miscellaneous documents

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Overview of Gram negative bacteria, fungi, and mycobacterial species in paediatric haemato-oncology BSI data

GGC versus four comparator units

Background

In his first Expert Report, Mr Mookerjee lists the Gram negative bacteria (GNB) and fungi present in the Schiehallion blood stream infection (BSI) data (Bundle 21, vol 1, par. 8.1.16, p. 25-26). In her oral evidence, Dr Mumford stated that she instructed Mr Mookerjee to focus on these species. Presenting this list to the Inquiry clearly implies that these organisms are rare/unusual, and that the mere detection of them must therefore point directly to a source in the hospital environment that has arisen due to deficits or negligence on the part of NHS GGC.

Through FOI requests, Mr Mookerjee and Dr Mumford also obtained lists of organisms detected in paediatric haemato-oncology patient cohorts at four other hospitals, and Dr Mumford confirmed in her oral evidence that she reviewed these lists. When asked whether there were any 'environmental' organisms seen at the other sites that did not occur in GGC, she stated (with the help of Mr Mackintosh) that there might have been a few but the numbers were so low that it would not have impacted on the results of their analysis.

Approach

Here, I examine the lists of organisms reported in the FOI returns from the four comparator hospitals (referred to as Site A, Site B, Site C, and Site D) to assess the accuracy of the statement that rare/unusual/environmental organisms occurred predominantly in GGC but not in the other hospitals. I first used the same filtering criteria as Mr Mookerjee described in his first report, removing all Gram positive bacteria, those Gram negative bacteria that were not identified to genus level (e.g. 'Gram negative bacillus'), and all species belonging to the genera *Escherichia*, *Campylobacter*, *Fusobacterium*, *Haemophilus*, *Moraxella*, and *Neisseria* (as per Dr Mumford's instruction to Mr Mookerjee). Like Mr Mookerjee, I kept the fungal entries.

However, unlike Dr Mumford and Mr Mookerjee, I also look at nontuberculous mycobacteria, as these organisms are well known to occur in water distribution systems and have been a focus of the SHI due to cases of *Mycobacterium chelonae* at the QEUH. Some of the other sites reported 'acid fast bacilli', and I included those as well. The vast majority of acid fast bacilli are mycobacterial species, and such a result would be interpreted as a presumptive mycobacterial species pending confirmation. The caveat is that there is a small chance that these acid fast bacilli isolates belonged to other rare organisms (e.g. *Nocardia, Gordonia, Rhodococcus, Tsukamurella*), none of which appeared in the Schiehallion BSI data.

Finally, to allow comparison across the sites, I limit the organism identification to species level rather than subspecies. This means that entries in the GGC data for '*Enterobacter cloacae* ssp *cloacae'* were recoded to '*Enterobacter cloacae*', since treating the subspecies as a distinct organism unique to GGC would not be accurate if other sites only reported to species level. Similarly, GGC's identification method cannot distinguish between *Aeromonas hydrophila* and *Aeromonas caviae* whereas other sites report these individually, so for comparability, all were recoded to *Aeromonas hydrophila/caviae*.

Overview of Gram negative bacteria, fungi, and mycobacteria across all sites

All comparator hospitals had Gram negative bacteria and fungal species that would be considered rare, unusual, and/or environmental by Dr Mumford / Mr Mookerjee's definition.

Across all five sites, a total of 105 different organisms met Dr Mumford and Mr Mookerjee's filtering criteria: 88 Gram negative bacterial species and 17 fungi. In addition, there were five different confirmed mycobacterial species, an additional group identified only to genus level (*Mycobacterium* species) plus the category 'acid fast bacilli'. Table 1 shows the number of different organisms in each category (Gram negative bacteria, fungi, mycobacteria) that were found in the data from each site, along with the total number of cases in parentheses.

Table 1. Number of different species of Gram negative bacteria, fungi, and mycobacteria in BSI data from each site (total number of cases 2015-2022 in parentheses*).

Site	Gram negative bacteria	Fungi	Mycobacteria
GGC	36** (169)	5 (18)	1 (1)
Site A	33 (230)	13 (35)	5 (11)
Site B	39 (331)	5 (31)	3 (14)
Site C	24 (149)	3 (7)	2 (4)
Site D	21 (110)	5 (16)	none

* Number of cases must be interpreted with caution due to inconsistencies in whether/how each site deduplicated the BSI data in response to the FOI request. In particular, Site B clearly stated that they did not deduplicate their data.
** The Mookerjee list for GGC has 37 different GNBs because *Enterobacter cloacae* and *Enterobacter cloacae* ssp *cloacae* are listed separately.

Of the 88 different Gram negative bacterial species found across the five sites, fewer than half were detected at any one site. GGC saw 36 out of 88 GNB species, meaning 52 'environmental/rare/ unusual' GNBs were seen elsewhere but not in GGC. Similarly, GGC saw 5 out of 17 fungal taxa and one out of six Mycobacteria species (plus no acid fast bacilli).

Of the 36 GNB species seen in GGC, 21 were also seen at one or more of the other sites, as were three of the yeasts and *Mycobacterium chelonae* (which also occurred at Site A and Site B, in higher numbers than in GGC). Table 2 below shows the organisms seen in the GGC BSI data that also occurred elsewhere, as well as those organisms seen across two or more comparators that did not occur in the GGC BSI data.

Table 3 shows the organisms detected only at a single site. Fifteen GNB species and two fungal species were seen only in GGC, but each of the comparators also saw numerous Gram negative bacteria and fungi that were not detected at any of the other four sites: 14 GNB and five fungal species were unique to Site A, 14 GNB and one fungal species were unique to Site B, six GNB species were unique to Site C and five GNB species were unique to Site D. As expected, larger hospitals with higher numbers of beds, admissions, and positive blood cultures, as well as more complex referred patients, have longer lists of 'rare/unusual/environmental' organisms.

Table 2. Organisms seen at multiple sites

In GGC and elsewhere	Not in GGC but in 2+ comparators
In all four comparators:	*Acinetobacter* species
Enterobacter cloacae	*Aeromonas* species
Klebsiella oxytoca	*Bacteroides fragilis*
Klebsiella pneumoniae	*Capnocytophaga* species
Pseudomonas aeruginosa	*Enterobacter* species
Stenotrophomonas maltophilia	*Klebsiella* species
	Klebsiella variicola
Candida albicans	*Pantoea agglomerans*
Candida parapsilosis	*Proteus mirabilis*
	Pseudomonas species
In two or three of the comparators:	*Veillonella* species
Achromobacter species	
Acinetobacter baumannii	*Candida krusei*
Acinetobacter ursingii	*Candida lusitaniae*
Aeromonas hydrophila/caviae	*Candida* species
Citrobacter freundii	*Rhodotorula* species
Pantoea species	Yeast (undefined)
Rhizobium radiobacter	
Serratia liquefaciens	
Serratia marcescens	
Mycobacterium chelonae	
In one of the comparators	
Burkholderia cepacia group	
Chryseobacterium species	
Delftia acidovorans	
Elizabethkingia miricola	
Enterobacter cloacae complex	
Pseudomonas stutzeri	
Roseomonas mucosa	
Candida tropicalis	

Table 3. Organisms seen only at a single site.

GGC	Site A	Site B
Gram negative bacteria	Gram negative bacteria	Gram negative bacteria
Achromobacter denitrificans	*Alcaligenes* species	*Acinetobacter calcoaceticus*
Acinetobacter baumannii complex	*Bacteroides* species	*Acinetobacter nosocomialis*
Brevundimonas species	*Bacteroides stercoris*	*Acinetobacter pittii*
Burkholderia cepacia	*Comamonas* species	*Bacteroides ovatus*
Chryseomonas indologenes	*Delftia* species	*Capnocytophaga sputigena*
Citrobacter braakii	*Eikenella* species	*Enterobacter bugandensis*
Citrobacter koseri	*Enterobacter aerogenes*	*Enterobacter kobei*
Citrobacter youngae	*Salmonella* species	*Enterobacter xiangfangensis*
Cupriavidus pauculus	*Ochrobactrum* species	*Kingella kingae*
Elizabethkingia meningoseptica	*Proteus* species	*Leclercia adecarboxylata*
Elizabethkingia species	*Raoultella* species	*Pseudomonas oryzihabitans*
Enterobacter cancerogenus	*Rhizobium* species	*Pseudoxanthomonas* species
Enterobacter hormaechei	*Roseomonas* species	*Psychrobacter sanguinis*
Pseudomonas putida	*Serratia* species	*Salmonella enteritidis*
Sphingomonas paucimobilis		
	Fungi	Fungi
Fungi	*Candida glabrata*	*Saccharomyces cerevisiae*
Candida fermentati	Fungus (undefined)	
Rhodotorula mucilaginosa	*Magnusiomyces capitatus*	Mycobacteria
	Malassezia species	*Mycobacterium ratisbonense*
	Pichia species	
	Trichosporon species	
	Mycobacteria	
	Mycobacterium fortuitum	
	Mycobacterium mucogenicum	
	Mycobacterium species	

Site C	Site D
Gram negative bacteria	Gram negative bacteria
Morganella morganii	*Leptotrichia* species
Ochrobactrum anthropi	*Parabacteroides distasonis*
Pantoea eucrina	*Pseudomonas mendocina*
Pseudomonas monteilii	*Raoultella ornithinolytica*
Stenotrophomonas acidaminiphila	*Salmonella arizonae*
Wautersiella falsenii	
Mycobacteria	
Mycobacterium smegmatis	

Blood stream infections due to Mycobacteria or presumptive mycobacteria occurred at all hospitals except Site D, and more frequently than in GGC. These cases included five named species (*M. chelonae, M. fortuitum, M. mucogenicum, M. ratisbonense, and M. smegmatis*), cases identified to genus level only (*Mycobacterium* species), as well as cases identified as 'acid fast bacilli' (presumptive mycobacteria). GGC saw a case of *M. chelonae* in the Schiehallion unit but no cases of the other mycobacterial species (Table 4).

Table 4. Number of Mycobacterium species BSI cases across GGC and the comparator sites, 2015-2022. Numbers in square brackets show total positives (no deduplication).

Organism	**GGC**	**Site A**	**Site B**	**Site C**	**Site D**
Mycobacterium chelonae	1 [2]*	4 [4]	[2]		
Mycobacterium fortuitum		1 [5]			
Mycobacterium mucogenicum		2 [3]			
Mycobacterium ratisbonense			[8]		
Mycobacterium smegmatis				1	
Mycobacterium species		2 [2]			
Acid fast bacilli (unspecified)		2 [5]	[4]	[3]	

* This includes only the infection episode linked directly to 2A. Expanding the definition to include the episode linked to 3B would increase this number to 2 [4], but we do not know how case numbers at the other sites would change if the location restrictions were similarly expanded

Caveat

This summary looks mainly at the numbers of different species detected. While Tables 1 and 4 also list the number of cases, these must be interpreted with caution given inconsistencies in whether/how the different sites deduplicated their data.

Throughout his reports and in his oral evidence, Mr Mookerjee claimed that the data from GGC and from all comparator sites were deduplicated in the same way so as not to count repeated positives taken within a 14-day period. However, when pressed by Mr Mackintosh, he was unable to clearly explain whether this was 14 days from the first or the latest positive sample. His approach with the GGC data, i.e. to use the date of first positive, deviates from standard practice and would have over-counted episodes in GGC.

Looking at the FOI returns from each of the four comparators, it was immediately and abundantly clear that Mr Mookerjee misunderstood or misrepresented the data that each site provided. Mr Mookerjee's FOI request was unclear and complex, asking for data to be agglomerated by year, organism, and sampling site, but then also asking for numbers to be provided for total positives as well as 'de-deduplicated numbers for same infection episode', without defining what he means by 'episode'. No two sites answered in the same way:

- Site A provided the most detailed return, including all information requested. It is possible to determine both the total positives and the deduplicated episodes from this data set, though the column with deduplicated data is simply called 'Episode14Day' so it is not possible to determine whether this was 14 days from the first or latest sample.

- Site B provided only totals by organism and by year, with no agglomeration by sampling site. Crucially, they also stated the following: '*Please note that where you request total and de-duplicated organisms by "episode". Telepath does not carry data on what constitutes an 'episode' so we have been unable to provide that part*.' In short, the data from Site B is for total positives, and since there is no information on the collection date or patient, it is not possible to deduplicate this data set. Furthermore, the Site B data set carried a bold, red warning that infection data was only available from 16th October 2016 onwards, so Mr Mookerjee's 2016 infection rate for that site is blatantly wrong, as he divided the number of infections seen in 2.5 months by the total admissions for the whole year.

- Site C provided totals by year, then by site, then by organism. If there was deduplication, it appears to have been within sample types, not across them (i.e. if a patient had blood taken from both the red port and the white port on their line, these would not be identified as duplicates). At best, the deduplication is only partial, and it is not possible to fully deduplicate based on the information provided

- Site D provided only deduplicated totals. There is no sampling site information, nor is it possible to determine the total number of positives. Regarding deduplication, they stated the following: 'We have attempted to de-duplicate these samples, but we are unable to guarantee this is 100% accurate as patients can send multiple blood culture samples and can have multiple organisms from blood culture bottles.'

Given these inconsistencies in the data returns, I did not attempt to calculate rates of infections for the different organisms listed above. Such an exercise is not possible with these data.

Conclusions

- Contrary to Dr Mumford's and Mr Mackintosh's assertion, Gram negative and fungal organisms that would be considered rare/unusual/environmental by Dr Mumford's definition are commonly seen across all comparator sites. These organisms are not unique to or more prevalent in the BSI data from GGC.

- Mycobacterial species were observed at all sites except Site D, and the numbers of infections observed in GGC were not higher than elsewhere, even taking into account the caveats surrounding how other sites deduplicated their data.

- Focusing only on the list of organisms seen at GGC without providing the broader context, namely the lists of organisms seen at other sites, is highly prejudicial and paints an inaccurate picture of GGC having higher infection rates and a greater diversity of 'rare/unusual/environmental' organisms than the comparator hospitals. The approach taken by Dr Mumford, Ms Dempster, and Mr Mookerjee is clearly biased towards a predetermined narrative.

- This exercise exposed more fundamental flaws in Mr Mookerjee's analysis and oral evidence.

SCOTTISH HOSPITALS INQUIRY

Response to

‘Overview of Gram-negative bacteria, fungi, and mycobacterial species in paediatric haemato-oncology BSI data’ and ‘Glasgow 4 – Precognition’

By D. Chaput

Report prepared for the Scottish Hospitals Inquiry

Date of Submission: 28 May 2025

Dr Sara Mumford, MB. BS., MSc., FRCPath., SFFMLM.

The terms of that Restriction Order are published on the Inquiry website.

This report is written in response to Dr Chaput's two reports entitled 'Overview of Gram negative bacteria, fungi, and mycobacterial species in paediatric haemato-oncology BSI data' and 'Glasgow 4 – Precognition' which has more recently been turned into a statement.

1. The choice of organisms was based on organisms that are known to be associated with the environment, particularly water, and were found in blood cultures taken from paediatric haemato-oncology patients (the Schiehallion cohort). It was not implied or suggested that all were rare organisms but many are rarely seen causing clinical opportunistic infection. The methodology was discussed between the expert group and the way forward agreed.
2. In paragraph 21 of her statement, Dr Chaput suggests that only including the organisms actually seen at QEUH/RHC in the expert reports is prejudicial and inaccurate. I would argue that the analysis carried out by Mr Mookerjee suggests otherwise, as he has included all environmental organisms seen in blood cultures in the comparator sites and shown that the rate of infection is higher at QEUH/RCH in the Schiehallion cohort than in paediatric haemato-oncology patients at the peer comparator sites.
3. Having reviewed Mr Mookerjee's workings on the data analysis, I find that contrary to Dr Chaput's hypothesis on the exclusion of organisms from the comparator sites data, the same criteria to remove organisms which are enteric in nature (*Escherichia coli*, *Campylobacter*, *fusobacterium, haemophilus, moraxella, Neisseria)* was used but all other organisms, including fungi were left in the calculation.
4. At the Glasgow III hearing, having reviewed Mr Mookerjee's paper, I was under the impression that he had removed organisms from the comparator sites data which did not appear in the Schiehallion data. However, having now reviewed his workings, it is clear that all organisms were included. To illustrate this, the following table, taken from Mr Mookerjee's workings shows Dr Chaput's comparator site A (GOSH in Mr Mookerjee's paper). Similar evidence for the other comparator sites also exists.

Row	Labels	Designation	2015	2016	2017	2018	2019	2020	2021	2022
Achromobacter	sp.	GN	4		6			2	1	
Acinetobacter	baumannii	GN								3
Acinetobacter	sp.	GN	2	2	1	1	1	7	3	1
Aeromonas	sp.	GN					2			4
Alcaligenes	sp.	GN							2	
Bacteriodes	stercoris	GN		1						
Bacteroides	fragilis	GN				3				
Bacteroides	sp.	GN							1	
Candida	albicans	Fungi	1	6	3		2			1
Candida	glabrata	Fungi	2	9					8	1
Candida	krusei	Fungi			9	2				
Candida	parapsilosis	Fungi	7		1			10	1	2
Candida	sp.	Fungi	7							
Candida	tropicalis	Fungi				1			2	
Capnocytophaga	sp.	GN					3			
Chryseobacterium	sp.	GN	1							
Citrobacter	freundii	GN	4		2				1	
Comamonas	sp.	GN								1
Delftia	sp.	GN			7					1
Eikenella	sp.	GN		1			1			
Enterobacter	aerogenes	GN	6	2		2				
Enterobacter	cloacae	GN	5	8	4	6	10	8	3	2
Enterobacter	sp.	GN	1	1	3	3	1	8	4	2
Escherichia	coli	GN	7	8	10	6	4	2		12
Fungus	(undefined)	Fungi				1				
Fusobacterium	sp.	GN				1			1	
Haemophilus	sp.	GN				1				
Klebsiella	oxytoca	GN	6	4		1	7	1	5	5
Klebsiella	pneumoniae	GN	2	8	14	1	15	10	6	6
Klebsiella	sp.	GN					2			
Magnusiomyces	capitatus	Fungi			7					
Malassezia	sp.	Fungi	2							
Moraxella	catarrhalis	GN	1							
Moraxella	sp.	GN			4					
Neisseria	meningitidis	GN		1						
Neisseria	sp.	GN		2	1			1		
Ochrobactrum	sp	GN					1			
Ochrobactrum	sp.	GN			1				1	
Pantoea	sp.	GN			4		1		5	2
Pichia	spp.	Fungi							4	
Proteus	sp.	GN							2	
Pseudomonas	aeruginosa	GN	3	6	10	10	24	24	20	5
Pseudomonas	sp.	GN			2		12	3	5	
Raoultella	sp.	GN		1						
Rhizobium	sp.	GN	2			3				
Rhodotorula	sp.	Fungi								1
Roseomonas	sp.	GN		1						
Serratia	marcescens	GN	1	1		1	1			2
Serratia	sp.	GN	3	1						
Stenotrophomonas		GN	2							
Stenotrophomonas	maltophilia	GN		4	2	5	13	21	15	10
Trichosporon	sp.	Fungi				4				
Veillonella	sp.	GN			1			1		
Yeast		Fungi	1							
Yeast	(undefined)	Fungi		2					2	
		Total	62	58	77	44	96	95	91	49

5. As can be clearly seen the list includes all of the organisms which Dr Chaput has suggested were removed. The totals match those seen in the table at 8.3.6 of Mr Mookerjee's report[1] and demonstrate that he used all of the data provided by the comparator sites included in his analysis after removal of the enteric organisms.
6. At the Glasgow III hearing I was clear that there should not be a background rate of the environmental organisms. This would apply to the comparator sites as much to QEUH/RHC and no further implication was made. In paragraph 22 of her statement Chaput appears to be drawing conclusions about the implications of what I said with no evidence to substantiate this.

[1] Bundle 21, Paper 1, page 3

7. At no point does the report written by myself and Ms Dempster suggest that the diversity of organisms is greater at QEUH/RHC than at the comparator sites.

8. I have never claimed that the environmental organisms examined in Sid Mookerjee's analysis are only seen at QEUH/RHC. This is clearly not the case. I have not defined environmental organisms in any unusual manner. This is evidenced by the HPS[2] and CNR[3] reports which also use very similar organism data sets.
9. Dr Chaput's report makes claims about the data used in Mr Mookerjee's report which do not stand up to analysis. All organism data from the comparator sites were included in Mookerjee's analysis and therefore the conclusions drawn in Dr Chaput's report cannot be substantiated.

[2] Review of NHS GG&C Infection Outbreaks in the Paediatric Haemato-oncology Data (Bundle 7, Document 6, Page 214)

[3] Bundle 6, Document 38, page 975

From: Kirsten McMillan
To: Kirsten McMillan
Subject: FW: Request for Information on Proactive Surveillance of Environmental Organisms in England
Date: 09 May 2025 16:53:59

From: Linda Dempster <[redacted]>
Sent: 06 May 2025 07:28
To: Mansi Khanna <[redacted]>
Cc: Fred Mackintosh <[redacted]>; Helen Lawrence <[redacted]>; MUMFORD, Sara (MAIDSTONE AND TUNBRIDGE WELLS NHS TRUST) <[redacted]>
Subject: Re: Request for Information on Proactive Surveillance of Environmental Organisms in England

Good morning Mansi

I don't think I can add anything to my previous reply. Our response was based on our professional expertise in IPC- as stated in our evidence.

Kind regards
Linda

Sent from my iPhone

> On 30 Apr 2025, at 17:04, Mansi.Khanna[redacted] wrote:
>
> Dear Linda,
>
> I hope you are well.
>
> Firstly, apologies for the delay in getting back to you, and thank you again for your response to our earlier request. I am writing to follow up on behalf of Counsel following a review of the evidence and closing submissions.
>
> In particular, during your oral evidence, you indicated that proactive surveillance of environmental organisms may have acted as an early warning system, and that such surveillance was, to your knowledge, undertaken widely in England. NSS has subsequently raised a query regarding this point, noting that no specific examples were provided during evidence.
>
> **Relevant Excerpt from your Transcript (Columns 112–114): Transcript - Dr Sara Mumford and Linda Dempster - 12.11.2024 | Hospitals Inquiry**

“I think all trusts, well, certainly where I’ve worked, we would be collecting data broader than just a set of alert organisms. We would be looking at infections … it was not an unusual ask at all.”

Further, to assist you in considering the query raised, we have also set out the relevant excerpts from NSS’s closing submissions below.

Relevant excerpts: NSS Closing Submissions: Page 59 to 61 - Core Participant Closing Submissions to the Inquiry - Glasgow 3 | Hospitals Inquiry

Paragraph 36: NSS notes that evidence suggested proactive surveillance of environmental organisms is widespread in England and is not an unusual task, but no specific examples were given. NSS submits that if reliance is to be placed on the existence of such surveillance, further evidence would be required.
Paragraph 39: NSS refers to the importance of clear evidence in support of processes such as surveillance or derogations and notes previous comments regarding the need for detailed and specific information.

We would be very grateful if you could please review these materials and, if possible, provide examples of specific trusts or health boards where proactive surveillance of environmental organisms was in place at the relevant time.

In light of current time pressures, we would be grateful if you could provide this information by **7 May 2025**. If this timeframe is likely to pose any difficulty, please do let us know at your earliest convenience so that we can make appropriate arrangements.

Please do let me know if you would like any further information or assistance.

Kind regards,
Mansi

Mansi Khanna
Legal Support Officer | Scottish Hospitals Inquiry

email: Mansi.khanna[redacted] **website:** www.hospitalsinquiry.scot
<image001.png>
@ScotHospInquiry |
<image002.png>
Scottish Hospitals Facebook |
<image003.png>
Scottish Hospitals Inquiry

<image004.png>

From: linda.j.dempster[redacted] <[redacted]>

Sent: 23 April 2025 12:46
To: Mansi Khanna <[redacted]>
Cc: Kirsten McMillan <[redacted]>; Helen Lawrence <[redacted]>; MUMFORD, Sara (MAIDSTONE AND TUNBRIDGE WELLS NHS TRUST) <[redacted]>
Subject: Re: Request for Information on Proactive Surveillance of Environmental Organisms in England

Dear Mansi

In response to the query below.

In our Microbiologist/IPC experience at several NHS Trusts, positive blood cultures are followed up clinically by Microbiologists and/or IPC teams. This will include the review of the patients and review of the source of infection. This does include environmental organisms. Microbiolgy/IPC store this data in a range of ways/systems and can look at data regarding clusters/connections/trends in high-risk patients and locations.

There will be established 'alert organism' surveillance and systems, such as IC Net, at hospital/Trust level to enable interrogation of data (positive samples). All microbiology laboratories in England (coserv) and Scotland (ECOSS) submit data on a monthly basis on positive diagnoses.

Annual reports on mandatory surveillance are available in England and Scotland. In England there are reference laboratories that do ongoing surveillance which can result in outbreak alerts.

UKHSA does undertake enhanced surveillance, from time to time, on certain diseases depending on the level of concern- invasive group A Strep is a good example of this, and currently Measles.

We do not believe that there is national data collection specifically for all environmental organisms.

Kind regards
Linda

Linda Dempster

From: Mansi.Khanna[redacted]
Sent: Friday, April 11, 2025 2:58 PM
To: linda.j.dempster[redacted]
Cc: Kirsten.McMillan[redacted]
Helen.Lawrence[redacted]

Subject: RE: Request for Information on Proactive Surveillance of Environmental Organisms in England

Dear Linda,

I hope this message finds you well.

I am writing to follow up on my email from 1 April regarding NSS' closing submission for the Glasgow 3 Hearings and their concerns raised in paragraphs 36 and 39.

Could you kindly provide any relevant reports or materials from national agencies in England that could support the existence of such systems around that time?

I understand that Dr. Mumford is occupied with some commitments at the moment, and I would be grateful if you could assist in this matter.

Many thanks & regards,

Mansi

Mansi Khanna

Legal Support Officer | Scottish Hospitals Inquiry

email: Mansi.khanna[redacted] **website:** www.hospitalsinquiry.scot

<image001.png>
@ScotHospInquiry |
<image002.png>
Scottish Hospitals Facebook |
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From: Mansi Khanna
Sent: 01 April 2025 16:11
To: MUMFORD, Sara (MAIDSTONE AND TUNBRIDGE WELLS NHS TRUST) <[redacted]>; linda.j.dempster <[redacted]>
Cc: Kirsten McMillan <[redacted]>; Helen Lawrence [redacted]
Subject: Request for Information on Proactive Surveillance of Environmental Organisms in England

Dear Linda and Sara,

I hope you are both well.

I am reaching out regarding NSS' closing submission for Glasgow 3 Hearings that were held from 19 August 2024 until November 2024. Specifically, NSS raised concerns at paragraphs 36 and 39 of their submission about the lack of examples demonstrating that, in 2016, a health board or NHS trust had established a proactive surveillance system for environmental organisms as an early warning mechanism. NSS noted that while such surveillance was stated to be widespread in England, no specific examples were provided (as noted in CTI Closing Submissions). They further suggested that if the Inquiry intends to rely on the existence of such surveillance in England, additional evidence should be heard on the matter.

Could you please provide any written material - such as reports by national agencies in England, that would support the existence of such proactive surveillance systems?

Please let me know if you need any further clarification. I appreciate your time and assistance on this matter.

Many thanks & regards,

Mansi

Mansi Khanna

Legal Support Officer | Scottish Hospitals Inquiry

email: Mansi.khanna[redacted] **website:** www.hospitalsinquiry.scot

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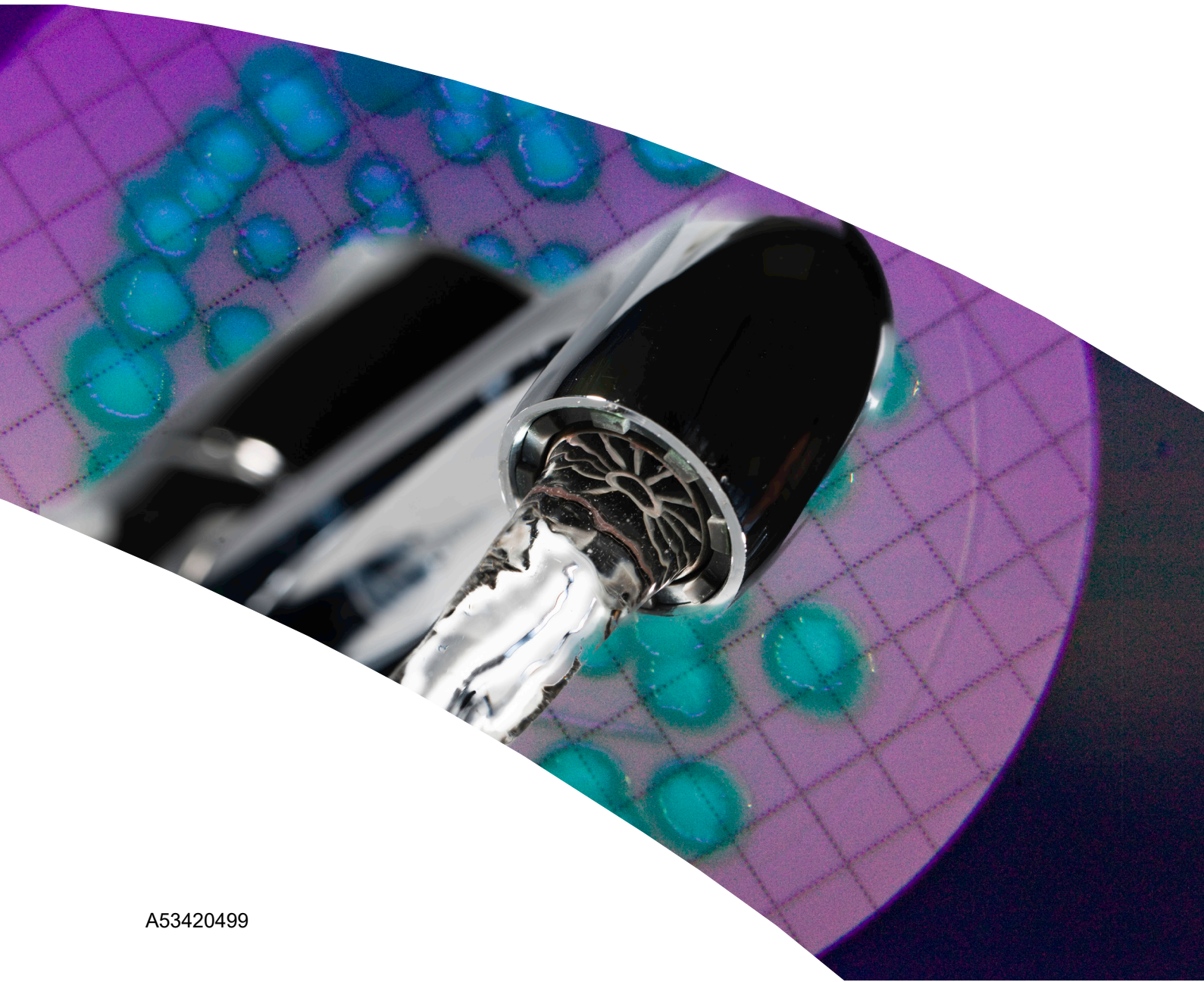
Department of Health

Water systems
Health Technical Memorandum 04-01: Addendum

Pseudomonas aeruginosa – advice for augmented care units



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Description	This addendum, aimed at all those involved with patient safety and specifically estates and facilities and infection prevention and control teams, focuses on specific additional measures to control/minimise the risk of P. aeruginosa. It may also have relevance to other opportunistic pathogens such as Stenotrophomonas maltophilia, Burkholderia cepacia and atypical mycobacteria.
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Water systems
Health Technical Memorandum 04-01: Addendum

***Pseudomonas aeruginosa* – advice for augmented care units**

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The Department of Health would like to thank all those who have helped to develop and produce this guidance, including all those who commented and sent contributions during the technical engagement phase.

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Contents

Executive summary

In recent years there has been an increase in published evidence relating to outbreaks and incidents in augmented care units related to *Pseudomonas aeruginosa*.

In March 2012, the Department of Health published 'Water sources and potential *Pseudomonas aeruginosa* contamination of taps and water systems: advice for augmented care units'. This addendum to Health Technical Memorandum 04-01 builds on and supersedes the March 2012 guidance.

The document is concerned with controlling/ minimising the risk of morbidity and mortality due to *P. aeruginosa* associated with water outlets and provides guidance on:

- assessing the risk to patients when water systems become contaminated with *P. aeruginosa* or other opportunistic pathogens;
- remedial actions to take when a water system becomes contaminated with *P. aeruginosa*;
- protocols for sampling, testing and monitoring water for *P. aeruginosa*; and
- forming a Water Safety Group (WSG) and developing water safety plans (WSPs).

The guidance is directed towards healthcare organisations providing patient care in augmented care settings. It is specifically aimed at Estates and Facilities departments and infection prevention and control (IPC) teams.

For the purposes of this document, the patient groups in an augmented care setting include:

a. those patients who are severely immunosuppressed because of disease or treatment: this will include transplant patients and similar heavily immunosuppressed patients during high-risk periods in their therapy;

b. those cared for in units where organ support is necessary, for example critical care (adult paediatric and neonatal), renal, respiratory (may include cystic fibrosis units) or other intensive care situations;

c. those patients who have extensive breaches in their dermal integrity and require contact with water as part of their continuing care, such as in those units caring for burns.

Glossary and list of abbreviations

Glossary

Alert organisms: Alert organisms are microorganisms that have the potential to cause harm and disease in individuals and which can cause an outbreak of infection in a hospital environment. An alert organism is identified by the microbiology laboratory and referred to the infection prevention and control (IPC) team for assessment of possible healthcare-associated acquisition and to identify any possible environmental/equipment sources.

Augmented care units/settings: There is no fixed definition of "augmented care"; individual providers may wish to designate a particular service as one where water quality must be of a higher microbiological standard than that provided by the supplier. While this document provides broad guidance, the water quality required will be dependent on both the type of patient and its intended use. Most care that is designated as augmented will be that where medical/nursing procedures render the patients susceptible to invasive disease from environmental and opportunistic pathogens such as *Pseudomonas aeruginosa* and other alert organisms. In broad terms, these patient groups will include:

a. those patients who are severely immunosuppressed because of disease or treatment: this will include transplant patients and similar heavily immunosuppressed patients during high-risk periods in their therapy;

b. those cared for in units where organ support is necessary, for example critical care (adult paediatric and neonatal), renal, respiratory (may include cystic fibrosis units) or other intensive care situations;

c. those patients who have extensive breaches in their dermal integrity and require contact with water as part of their continuing care, such as in those units caring for burns.

Biofilm: A biofilm is a complex layer of microorganisms that have attached and grown on a surface. This form of growth provides a niche environment for a wide range of microorganisms to interact and where the secretion of exopolysaccharides by bacteria will form an extracellular matrix for both bacteria and other unicellular organisms such as amoebae and flagellates to remain in a protected state.

Blind end (or dead end): A length of pipe closed at one end through which no water passes.

Colony forming unit: Unit that gives rise to a bacterial colony when grown on a solid medium; this may be a single bacterial cell or a clump of cells.

Dead-leg: A pipe supplying water to a fitting through which water flows only when there is draw-off from the fitting.

Estates and Facilities management: This title embraces the healthcare facilities themselves and the engineering and many other services contained therein. Maintenance and management of the buildings and engineering services is often referred to as "hard" FM (facilities management); activities such as catering, cleaning, sterile supply services, laundry and linen supply is often referred to as "soft" FM.

Flow straightener: A device inserted into the spout outlet of a tap to modify flow, take out turbulence and create an even stream of water (see photograph below).

Point-of-use filter: A device comprising a filter membrane that is fitted to water outlets such as taps and showers at the point of water delivery to retain bacteria.

Remediation: Any process that reduces the risk from harmful agents such as microorganisms.

Transmission: Any mechanism by which an infectious agent is spread from a person or environmental source to a susceptible person.

Water outlet: (In this document) refers mainly to taps and showerheads, but other outlets, as indicated by risk assessments, may be considered important.

Water Safety Group (WSG): A multidisciplinary group formed to undertake the commissioning and development of the water safety plan (WSP). It also advises on the remedial action required when water systems or outlets are found to be contaminated and the risk to susceptible patients is increased.

Water safety plan (WSP): A risk-management approach to the microbiological safety of water that establishes good practices in local water distribution and supply. It will identify potential microbiological hazards caused by *P. aeruginosa* and other opportunistic pathogens, consider practical aspects, and detail appropriate control measures. WSPs are working documents that need to be kept up-to-date and reviewed whenever organisations make changes to water supplies, uses of water and control measures.

Water supply [to the hospital]: The water supplied can be via**:**

- the mains water supply from the local water undertaker (water company);
- a hospital borehole;
- a combination of mains water and borehole supply;
- emergency water provision (bulk tankered water or bottled drinking water).

For definition of taps/TMVs, see Appendix 2.

List of abbreviations

cfu: colony forming units

DIPC: director of infection prevention and control

HCAI Code of Practice: 'The Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance'

IPC: infection prevention and control

MCA: milk cetrimide agar

MRD: maximum recovery diluent

PFI: private finance initiative

PHE: Public Health England

POU: point-of-use

TMV: thermostatic mixing valve

WRAS: Water Regulations Advisory Scheme

WSG: Water Safety Group

WSP: water safety plan

1.0 Introduction

1.1 This addendum to Health Technical Memorandum 04-01 is aimed at those involved with patient safety and specifically Estates and Facilities and infection prevention and control (IPC) teams.

1.2 It focuses on the specific additional measures to control/minimise the risk of *P. aeruginosa*, but may also have relevance to other opportunistic pathogens such as *Stenotrophomonas maltophilia*, *Burkholderia cepacia* and atypical mycobacteria.

1.3 The recommendations for the control of *Legionella* etc given in Health Technical Memorandum 04-01 remain extant.

1.4 Additional general requirements for the quality assurance of water systems including those within healthcare facilities should be followed (see the Health & Safety Executive's 'Legionnaire's disease: the control of legionella bacteria in water systems – Approved Code of Practice and guidance' and the NHS Premises Assurance Model).

NHS Premises Assurance Model

The NHS has developed, with the support of the Department of Health, the NHS Premises Assurance Model (NHS PAM), whose remit is to provide assurance for the healthcare environment and to ensure service-users are protected against risks associated with such hazards as unsafe premises.

It allows NHS organisations to better understand the effectiveness, quality and safety with which they manage their estate (including water safety) and how that links to the patient experience.

NHS PAM has been designed to apply to:

- NHS foundation trusts;
- NHS trusts;
- mental health trusts;
- ambulance trusts; and
- community trusts.

For more information on how to use the tool, visit http://www.dh.gov.uk/health/2013/01/nhs-pam

2.0 *Pseudomonas aeruginosa*: overview

Ecology

2.1 *P. aeruginosa* is a Gram-negative bacterium, commonly found in wet or moist environments. It is commonly associated with disease in humans with the potential to cause infections in almost any organ or tissue, especially in patients compromised by underlying disease, age or immune deficiency (see paragraph 2.3). Its significance as a pathogen is exacerbated by its resistance to antibiotics, virulence factors and its ability to adapt to a wide range of environments.

2.2 *P. aeruginosa* thrives in relatively nutrient-poor environments at a range of different temperatures and can become one of the species in biofilms where a slime layer binds a mixed bacterial population to surfaces. Although most bacteria will remain fixed within the biofilm, some will become detached resulting in free-floating (planktonic) forms that can cause contamination of the water layer above the biofilm.

Transmission

2.3 *P. aeruginosa* is an opportunistic pathogen that can colonise and cause infection in patients who are immunocompromised or whose defences have been breached (for example, via a surgical site, tracheostomy or indwelling medical device such as a vascular catheter). In most cases, colonisation will precede infection. Some colonised patients will remain well but can act as sources for colonisation and infection of other patients. As a microorganism that is often found in water, the more frequent the direct or indirect contact between a susceptible patient and contaminated water, and the greater the microbial contamination of the water, then the higher the potential for patient colonisation or infection.

2.4 Contaminated water in a hospital setting can transmit *P. aeruginosa* to patients through the following ways:

- direct contact with the water through:
  - ingesting
  - bathing
  - contact with mucous membranes or surgical site, or
  - through splashing from water outlets or basins (where the flow from the outlet causes splashback from the surface);
- inhalation of aerosols from respiratory equipment, devices that produce an aerosol or open suctioning of wound irrigations;
- medical devices/equipment rinsed with contaminated water;
- indirect contact via healthcare workers' hands following washing hands in contaminated water, from surfaces contaminated with water or from contaminated equipment such as reusable wash-bowls.

Source

2.5 It is generally accepted in the case of *Legionella* that the source of bacteria in hot- and cold-water systems is the incoming water supply and that it becomes a problem only if there is a failure of the recommended control measures (for example, maintenance of temperatures or water treatment regimens).

2.6 In contrast to *Legionella*, the origin of *P. aeruginosa* is less certain. Its presence becomes evident at outlets from the system (for example taps) and can be found within the last two metres before the point of discharge of water. Devices fitted to, or close to, the tap outlet (for example flow straighteners) may exacerbate the problem by providing the nutrients which support microbial growth, providing a surface area for oxygenation of

water and leaching nutrients. The source, therefore, could be:

- the incoming water supply from the water provider;
- the water supply within the building (both from the storage and distribution system), usually within biofilms;
- the waste-water system (see Breathnach et al. 2012); or
- via external contamination from:
  - clinical areas
  - outlet users
  - poor hygiene or processes during cleaning
  - splashback from contaminated drains.

2.7 Given this variety, the challenge for managers and staff is to risk-assess their particular operational practices in an attempt to minimise inoculation from any of these sources.

Management of control

2.8 Management of water systems to reduce the risk of microbial growth including opportunistic pathogens such as *Legionella* and *P. aeruginosa* is vital to patient safety. It requires surveillance and maintenance of control measures including temperature control, usage, cleaning and disinfection measures as identified within the risk assessment and *Legionella* control scheme for both hot- and cold-water systems.

2.9 To prevent growth of *P. aeruginosa*, controls are necessary to manage the water system before and after the outlet (comprehensive advice is given in Chapter 4).

2.10 Estates and facilities staff should ensure accurate records and drawings/diagrams showing the layout and operational manuals of the whole water system are available. These staff should have received adequate training and be fully aware of the extent of their responsibilities. Strict adherence to the recommendations in Health Technical Memorandum 04-01 will help to achieve this (see Chapter 4).

2.11 IPC teams should:

- ensure application of, and compliance with, the evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England (see Pratt et al. (2007));
- ensure best practice advice relating to wash-hand basins is followed to minimise the risk of *P. aeruginosa* contamination (see Appendix 1).

2.12 The 'Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance' (the HCAI code of Practice) sets out the criteria against which a registered provider's compliance with the requirements relating to cleanliness and infection control will be assessed by the Care Quality Commission. It also provides guidance on how the provider can interpret and meet the registration requirement and comply with the law. Criterion 2 states that providers should provide and maintain a clean and appropriate environment in managed premises that facilitates the prevention and control of infections.

2.13 IPC teams should continue to monitor clinical isolates of *P. aeruginosa* in risk-assessed augmented care units as an alert organism and be aware of possible outbreaks or clusters of infection with this microorganism.

3.0 Design and selection of water outlets and fittings

3.1 With the change in focus towards improving the patient environment and minimising the risk of healthcare-associated infections, there has been an increase in the provision of single-bed rooms with en-suite facilities. Additionally, to promote good hand hygiene, wash-hand basin provision has increased significantly in all clinical areas. However, in many situations this has led to underused water outlets and low water throughput. Such outlets form a greater risk of contamination by *P. aeruginosa* than those that are used more frequently.

3.2 Water services have become more complex. Every effort should be made when planning, designing and installing new or modified systems to minimise and remove potential hazards (for example oversized water storage tanks, flexible hoses, stagnant water, poor temperature control, long branch pipes and dead-legs), as well as enabling access for monitoring and maintenance. Adapting existing systems to improve safety is almost always the more expensive solution.

3.3 In new and existing premises, therefore, it is essential that the needs of individual patient washing and bathing requirements are carefully considered. In new premises, the provision, correct siting and installation of showers and wash-hand basins, particularly in accommodation where patients are unlikely to make use of them, requires assessment. For existing premises, and subject to a risk assessment, permanent removal of existing outlets and their associated pipework should be considered.

3.4 Tap design has evolved. In older installations, thermostatic control of water temperature was achieved by a separate thermostatic mixing valve (TMV) (commonly called a t-shaped TMV), typically located behind the sanitary assembly panel to which a wash-hand basin or other assembly was fitted, which then supplied water to the hot connection of a manual mixing tap or separate tap (see Figure 4). Many new installations now include taps of a modern design with integral TMVs. They are usually manually controlled (on and off) and can be adjusted to further reduce outlet temperature to fully cold. For some applications, remote sensor-operated taps are available (many sensor taps also have the option of auto-flushing programmes and can be linked to the hospital's building management system). In some instances these developments have led to a more complicated internal tap design which may increase the need for additional routine maintenance (including decontamination) to mitigate the risk of contamination by *P. aeruginosa*.

3.5 The choice and type of water outlets for the augmented care setting is therefore important (see Appendix 2). This choice should be based on a risk assessment of infection-control and scalding issues.

3.6 There is some evidence that the more complex the design of the outlet assembly (for example, some sensor-operated taps), the more prone to *P. aeruginosa* colonisation the outlet may be (see Berthelot et al. 2006).

3.7 In intensive care and other critical care areas, where patients are unlikely to be able to use the wash-hand basins, the installation of non-TMV mixing taps may be the preferred control option following a risk assessment (see paragraph 1 in Appendix 2).

Note:

For clinical wash-hand basins, Health Building Note 00-10 Part C – 'Sanitary assemblies' (formerly Health Technical Memorandum 64) recommends integral thermostatically controlled water using either a single-lever tap or a sensor tap for most applications and settings. If risk assessment justifies a different tap assembly for clinical wash-hand basins in augmented care settings, then derogation from Health Building Note 00-10 Part C may be considered so long as it is approved by the Water Safety Group (WSG).

3.8 In accordance with Health Technical Memorandum 04-01 Part A, TMVs should be fitted where risk assessment has shown vulnerable patients are at risk of scalding. This should be considered when planning/designing new builds or refurbishments. A TMV that is integral to the body of the tap/shower is preferred, as it is designed to always draw cold water through every time the outlet is used, thus helping to minimise the risk of stagnation.

Note:

Scalding risk assessments should form part of the water safety plan (WSP) before any decision is made on the method of scalding risk control (see paragraphs 4.11–4.26).

3.9 Owing to their high surface-area-to-volume ratio and location at the tap outlet, certain designs of flow straightener may present a greater surface area for colonisation and support the growth of organisms. Therefore, when selecting new taps, where possible flow straighteners should be avoided/not included. Health Building Note 00-09 also advises against using aerators in outlets.

3.10 If retro-fitting new taps, it is important to ensure that they are easy to use and practical for the existing space.

3.11 For guidance on replacing taps, see paragraph 4.49(k).

4.0 Operational management

Note:

This addendum focuses on the specific additional measures to control/minimise the risk of *P. aeruginosa*, but may also have relevance to other opportunistic pathogens such as *Stenotrophomonas maltophilia, Burkholderia cepacia* and atypical mycobacteria. The recommendations for the control of *Legionella* given in Health Technical Memorandum 04-01 remain extant; however, the operational management processes outlined in this addendum may also assist in the implementation of Health Technical Memorandum 04-01 Part B.

Introduction

4.1 Healthcare organisations have an explicit duty under the Health and Safety at Work Act etc 1974 to assess and manage the risks posed by water systems on their premises. In accordance with the HCAI Code of Practice, the healthcare organisation's chief executive is responsible for having systems in place to manage and monitor the prevention and control of infection. These systems use risk assessments and consider how susceptible patients are, and any risks that their environment and other users may pose to them. Ensuring these elements are in place will assist the organisation to fulfil its duties in relation to the provision of safe water systems. A programme of audit should be in place to ensure that key policies and practices are being implemented appropriately. This will inform the organisation's assurance framework.

The Water Safety Group

4.2 The WSG is a multidisciplinary group formed to undertake the commissioning and development of the WSP. It also advises on the remedial action required when water systems or outlets are found to be contaminated and the risk to susceptible patients is increased. The WSG may be a sub-group of the organisation's infection control committee or other relevant forum and could typically comprise:

- the director of infection prevention and control (DIPC);
- the IPC team;
- consultant medical microbiologist;
- the Estates and Facilities team (including hotel/cleaning services staff and the Responsible Person (Water));
- senior nurses from relevant augmented care units.

The chair of the group will be a local decision.

4.3 Irrespective of who chairs the group, they will be responsible for ensuring it identifies microbiological hazards, assesses risks, identifies and monitors control measures, and develops incident protocols.

4.4 Episodes of colonisation or infection with *P. aeruginosa* that could be related to the water system should be reported by the IPC team to the chair of the WSG, who will be expected to initiate an appropriate investigation.

4.5 The WSG should always act in an appropriate and timely manner. Individual responsibilities should not be restricted by the need to hold formal meetings.

4.6 As part of its wider remit, the WSG should include representatives from areas where water may be used in therapies, medical treatments or decontamination processes (for example, hydrotherapy, renal, sterile services).

Assurance/governance

4.7 The WSG should be accountable to the DIPC and provide reports upwards, for example to the infection control committee (although it is acknowledged that accountability arrangements for the WSG will vary by healthcare provider). Irrespective of the route the healthcare provider decides, it is important that accountability should demonstrate effective governance and assurance.

4.8 The WSG should monitor any proposed developments on the design or installation of the water distribution system and check that they are:

- likely to minimise the risk to patients, especially those treated in augmented care settings;
- compliant with all extant legislation and DH policy and guidance.

4.9 All items of equipment that need to be attached to the water distribution system and which may be used in direct care on patients should be approved by the WSG.

4.10 The WSG will need to ensure that decisions affecting the safety and integrity of the water system do not go ahead without being agreed by them.

Note:

Where estates & facilities provider services are part of a contract (including PFI), it is essential that these providers participate fully in all aspects of estate & facilities management that can affect patients. This includes responding to specific requests from the IPC team and WSG, which may be in addition to relevant guidance and documentation.

Water safety plans (WSPs)

4.11 To assist with understanding and mitigating risks associated with bacterial contamination of water distribution and supply systems and associated equipment, healthcare providers should develop a WSP, which provides a risk-management approach to the microbiological safety of water and establishes good practices in local water usage, distribution and supply (see Figure 1). Those organisations with existing robust water management policies for *Legionella* will already have in place much of the integral requirements for developing a WSP.

4.12 The first step in the development of a WSP is to gain a comprehensive understanding of the water system, including the range of potential hazards, hazardous events and risks that may arise during storage, delivery and use of water. It may require an understanding of the quality and management of the water as provided and how that water is used. Fundamental to this and any subsequent investigation or review is the provision and availability of accurate records/schematic drawings.

4.13 With respect to *P. aeruginosa*, the WSP should identify areas within hospitals with at-risk patients and incorporate:

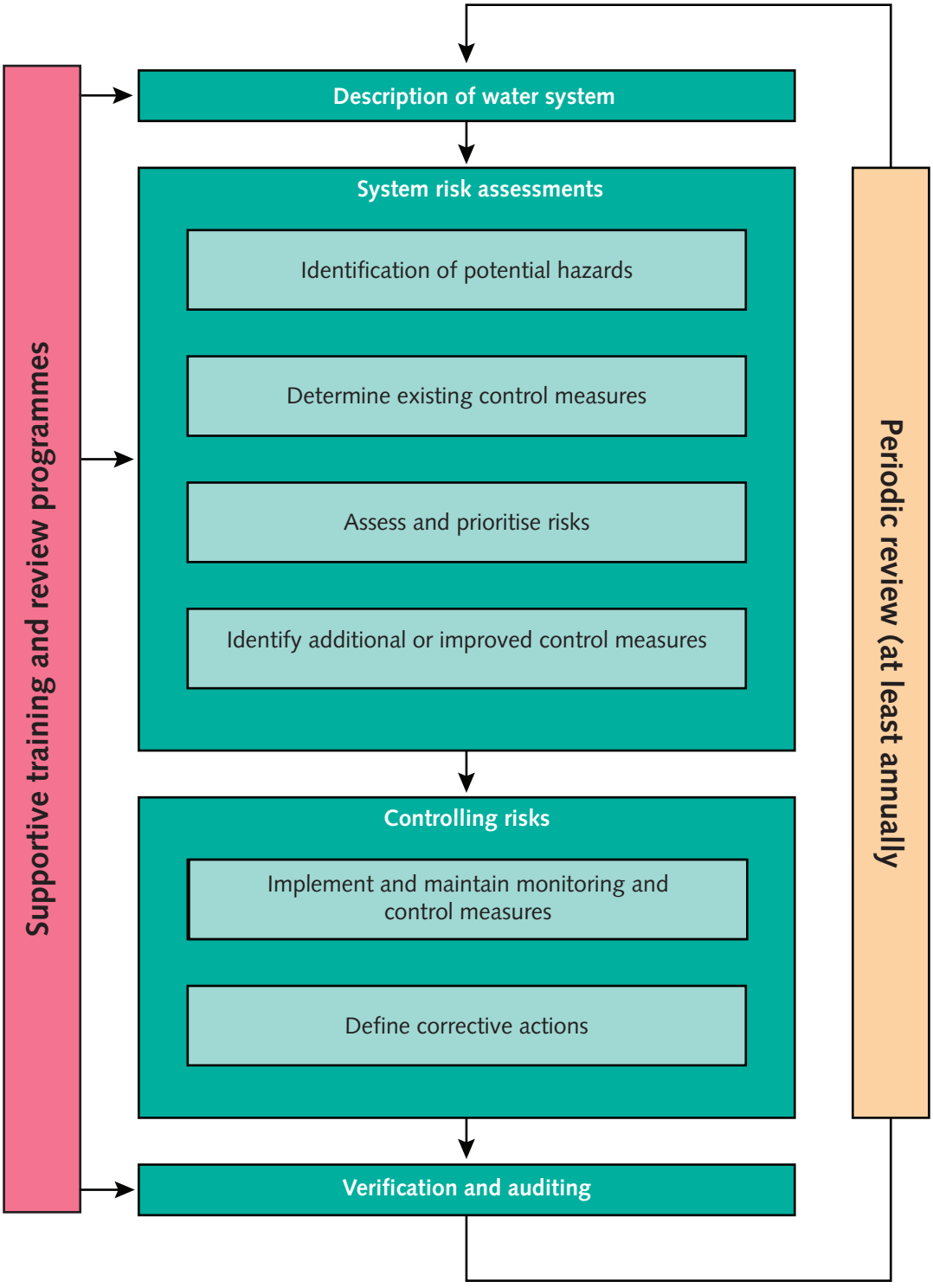
- clinical risk assessment to identify those settings where patients are at significant risk from *P. aeruginosa* contamination associated with water use and its distribution system;
- an engineering risk assessment of the water system;
- operational monitoring of control measures;
- links to clinical surveillance which can offer an early warning of poor water quality;
- plans for the sampling and microbiological testing of water in identified at-risk units (see Appendices 3 and 4).

Note:

Appendix 4 has been developed to provide technical guidance for a range of laboratories, including NHS, Public Health England (PHE) and commercial laboratories that have the capability and capacity to undertake water sampling and testing.

- changes to the water system to remedy high counts for *P. aeruginosa* and other opportunistic pathogens where appropriate;
- adjustments to clinical practice until remedial actions have been demonstrated to be effective;
- regular removal/cleaning/descaling or replacement of the water outlets, hoses and TMVs where there may be direct or indirect water contact with patients (see Health Technical Memorandum 04-01);
- amendments when changes are carried out and at annual review, including new builds, refurbishments and recently decommissioned clinical departments or units;
- documentation and record-keeping (best practice examples of the types of documentation and record keeping required are given in Health Technical Memorandum 04-01);
- a review of the results of any water testing regimen undertaken.

Figure 1 Documentation of management procedures (adapted from Figure 4.1 in WHO's 'Water safety in buildings')



4.14 The WSP should identify potential alert organisms and microbiological hazards caused by *Legionella*, *P. aeruginosa* and other opportunistic pathogens, consider practical aspects and detail appropriate control measures. The implementation of the WSP should be coordinated by the Responsible Person (Water). Implementation status reports should be periodically submitted to the WSG.

4.15 Development of the WSP will complement the existing operational management requirements of Health Technical Memorandum 04-01 and the work that has to be undertaken to fulfil the statutory requirement for a *Legionella* risk assessment and written scheme for its control and management.

4.16 The multidisciplinary group that developed the WSP also has a role in advising on the remedial action and communication required, should one or more outlets be found to be contaminated and where this may increase the risks to susceptible patients (see paragraph 4.49).

4.17 WSPs are working documents that need to be kept up-to-date and reviewed at least annually by the WSG and whenever incidents occur or organisations make changes to:

- water supplies and uses;
- control measures;
- its risk-management policies.

Risk assessments

4.18 The risk assessments that inform the WSP should identify potential microbiological hazards caused by *P. aeruginosa* and other opportunistic pathogens, and the hazardous events and risks that may arise during storage, delivery and use of water in augmented care settings.

4.19 They should identify actions to minimise these risks and ensure that appropriate sampling, monitoring and clinical surveillance arrangements are in place.

4.20 Risk assessments should be led by the DIPC, a consultant microbiologist or the IPC team representative and should consider:

- the susceptibility of patients from each type of water use (including ice);
- scalding risk;
- clinical practice where water may come into contact with patients and their invasive devices;
- the cleaning of patient equipment;
- the disposal of blood, body fluids and patients' wash-water;
- the maintenance and cleaning of wash-hand basins and associated taps, specialist baths and other water outlets;
- change in use (for example, clinical area changed to office accommodation or vice-versa) due to refurbishment or operational necessity;
- other devices that increase/decrease the temperature of water (for example, ice-making machines, water chillers) which may not be appropriate in augmented care settings;
- engineering assessment of water systems, including correct design installation, commissioning, maintenance and verification of the effectiveness of control measures (see also the Water Supply (Water Fittings) Regulations);
- underused outlets;
- flushing policy;
- the unnecessary use of flexible hoses and any containing inappropriate lining materials;
- sampling, monitoring and testing programme that needs to be put in place;
- the need for outlets at wash-hand basins that use sensor operation and TMVs (remote/integral);
- education and training.

4.21 Although not under the category of augmented care, situations will arise where surgical wounds may become contaminated from water outlets such as showers. Similarly the practice of soaking leg ulcers or syringing ears may require consideration of the microbiological quality of water used and will require local assessment.

4.22 The likelihood of hazardous events is influenced by the size and complexity of the water system and can be exacerbated by poor or over-

complicated design, construction, commissioning, operation and maintenance (see Chapter 3).

4.23 Once potential hazards and hazardous events have been identified, the severity of risk needs to be assessed so that priorities for risk management can be established. The risk assessment needs to consider the likelihood and severity of hazards and hazardous events in the context of exposure (type, extent and frequency) and the vulnerability of those exposed. Although many hazards may threaten water quality, not all will represent a high risk. The aim should be to distinguish between high and low risks so that attention can be focused on mitigating risks that are more likely to cause harm to susceptible patients who are experiencing augmented care (see Appendix 5 for an example risk assessment).

Action plan

4.24 When the risks have been identified, an action plan needs to be developed with defined roles and responsibilities, and agreed timescales to minimise these risks. The action plan should include:

- appropriate remedial actions, monitoring details and schedules for validation that show the remedial actions are effective and subject to ongoing verification. Completion dates should be defined.
- any training and competency issues required to ensure compliance with this guidance.

Documentation

4.25 All records pertaining to the risk assessment and action plan should be held and managed by the WSG.

Management of water safety risks and issues

4.26 Identified water safety risks and issues should be assessed, prioritised and included on a risk register for discussion and management by the WSG.

Protecting augmented care patients

4.27 The following paragraphs give examples of best practice advice aimed at protecting the susceptible patient and ensuring a safe environment:

a. For direct contact with patients, water of a known satisfactory quality should be used, that is:

   (i) water where testing has shown absence of *P. aeruginosa*; or

   (ii) water supplied through a point-of-use (POU) filter; or

   (iii) sterile water (for example, for skin contact for babies in neonatal intensive care units).

b. Water outlets should be reviewed where there may be direct or non-direct contact with patients. This may also include reviewing the need for the outlets/showers and their potential removal.

c. For patient hygiene, single-use wipes should be considered.

d. Rigorous reinforcement of standard infection control practices, including refresher training, should be implemented.

e. The cleaning of clinical wash-hand basins and the taps should be undertaken in a way that does not allow cross-contamination from a bacterial source to the tap (see Appendix 1) .

f. The cleaning of patient contact equipment (for example, tap handles, incubators, humidifiers, nebulisers and respiratory equipment) should be reviewed. Options would be to:

   (i) use single-use equipment;

   (ii) if locally reprocessed – even if used on the same patient – clean equipment with water of a known satisfactory quality (see (a) above);

   (iii) use single-use detergent wipes for cleaning incubators. If a disinfectant is used, it is important that it will not cause damage to the material of the incubator. Manufacturers' instructions should be followed. Disinfectants should not be used to clean incubators while occupied.

g. All other uses of water on augmented care units should be considered (for example, the use of ice machines, drinking water fountains, bottled water dispensers, wet shaving of patients who have a central venous catheter inserted into the jugular vein and washing patients with indwelling devices) and appropriate action/ changes to operational procedures taken.

Notes:

1. Tap water should not be used in neonatal units for the process of defrosting frozen breast milk.
2. Water features should not be installed in augmented care units.

h. All patient equipment should be stored clean, dry and away from potential splashing with water.

i. All preparation areas for aseptic procedures and drug preparation and any associated sterile equipment should not be located where they are at risk of splashing/contamination from water outlets.

j. All taps that are used infrequently on augmented care units should be flushed regularly (at least daily in the morning for one minute). If the outlet is fitted with a POU filter, the filter should not be removed in order to flush the tap unless the manufacturer's instructions advise otherwise. A record should be kept of when they were flushed. Some taps can be programmed to flush automatically; such flushing may be recorded on the building management system.

k. TMVs and associated components should be serviced, including descale and decontamination, at recommended intervals (see the TMV approval scheme at http://www.buildcert.com/tmv3.htm).

l. A TMV that is integral to the body of the tap/shower should be considered, as it will always draw cold water through every time the outlet is used, thus helping to minimise the risk of stagnation.

m. Where taps are designed to be easily removed for maintenance purposes, they should be periodically removed for descaling and decontamination and/or placed in a washer-disinfector (subject to the tap manufacturer's instructions).

n. It should be ensured that:

(i) accurate records and drawings cover all the hot- and cold-water systems and that they have been updated following any modification;

(ii) all services are properly labelled such that the individual services can be easily identified;

(iii) staff who are engaged in the installation, removal and replacement of outlets and associated pipework and fittings are suitably trained to prevent contamination of the outlet and water system.

Sampling and testing for *P. aeruginosa*

Note:

Experience to date has shown no meaningful correlation between the presence and count of *P. aeruginosa* and total viable counts (TVC) of bacteria. Consequently, the determination of TVC need not be done routinely in parallel with testing for *P. aeruginosa*.

P. aeruginosa in the water supply

4.28 *P. aeruginosa* may be present within the water storage, distribution and delivery systems and also in the water supplied to the hospital.

4.29 The sampling protocol (Appendix 3) is intended to help healthcare providers establish whether the water in augmented care units is contaminated with *P. aeruginosa* and, if it is, to help locate its origin and to monitor the efficacy of remedial measures.

4.30 Biofilms exist on plumbing materials throughout the water system. Where present, most *P. aeruginosa* will be found within two metres of the point of water delivery at the outlet – that is, after the water has left the circulation system.

4.31 While most bacteria are trapped within a biofilm, the biofilm will constantly generate bacteria that are released as free-floating individual cells (planktonic forms), and parts of the biofilm may slough off in clumps. The concentration of these planktonic bacteria will build up over time in the

water adjacent to a biofilm when the water is of a low flow rate or stagnant, but will be diluted as water is used and flows through the pipework or tap containing the biofilm.

4.32 It is essential to maximise the recovery of these free-floating planktonic bacteria that cause infection; therefore, water samples should be taken:

a. during a period of, preferably, no use (at least 2 hours or preferably longer); or

b. low use.

4.33 The same water outlet can give very different results if sampled at times of normal use and may be negative if water from the tap has been used before a sample is collected.

4.34 The first water to be delivered from the outlet (pre-flush sample) should be collected to assess the microbial contamination in the outlet.

4.35 If water flows over a biofilm containing *P. aeruginosa* located at or near the outlet, planktonic bacteria arising from that biofilm will be diluted and a subsequent sample will give low bacterial counts. If contamination is upstream in the system, this will not affect bacterial counts.

4.36 The sample obtained after allowing water to flow from an outlet is referred to as a "post-flush" sample (see paragraphs 12 and 13 in Appendix 3). Comparison of counts from pre- and post-flush samples can help locate the source of the *P. aeruginosa*. If a pre-flush sample gives a high count, subsequent paired pre- and post-flush samples should be tested to help locate the source of the contamination.

4.37 In order to be able to carry out the appropriate microbiological examinations on a sample and provide a meaningful interpretation of test results, it is essential that samples are collected in the correct manner using the correct equipment and that the sampling protocol in Appendix 3 is adhered to.

4.38 Protocols for microbiological examination of samples are provided in Appendix 4.

Where to sample water outlets

4.39 The water outlets to be sampled should be those that supply water which:

- has direct contact with patients;
- is used to wash staff hands; or
- used to clean equipment that will have contact with patients as determined by risk assessment.

When and how to sample water outlets

4.40 The outlets identified above should be sampled to provide an initial assessment of contamination levels. There is no need to sample all taps that are due to be sampled on the same occasion; samples can be taken in batches on separate occasions. It may assist the receiving laboratory if the sampling schedule is agreed beforehand (see Figure 2 and also Appendix 3).

Interpretation of *P. aeruginosa* test results

4.41 If test results are satisfactory (not detected), there is no need to repeat sampling for a period of six months unless there are changes in the water distribution and delivery systems components or system configuration (for example, refurbishments that could lead to the creation of dead-legs) or occupancy.

4.42 Water sampling could be undertaken within six months if there are clinical evidence-based suspicions that the water may be a source of patient colonisation or infection (that is, with *P. aeruginosa* or another potentially water-associated pathogen).

4.43 If tests show counts of 1–10 cfu/100 mL, refer to the WSG, who should risk-assess the use of water in the unit. Simultaneously, retesting of the water outlet should be undertaken (see Figure 2 and Note below).

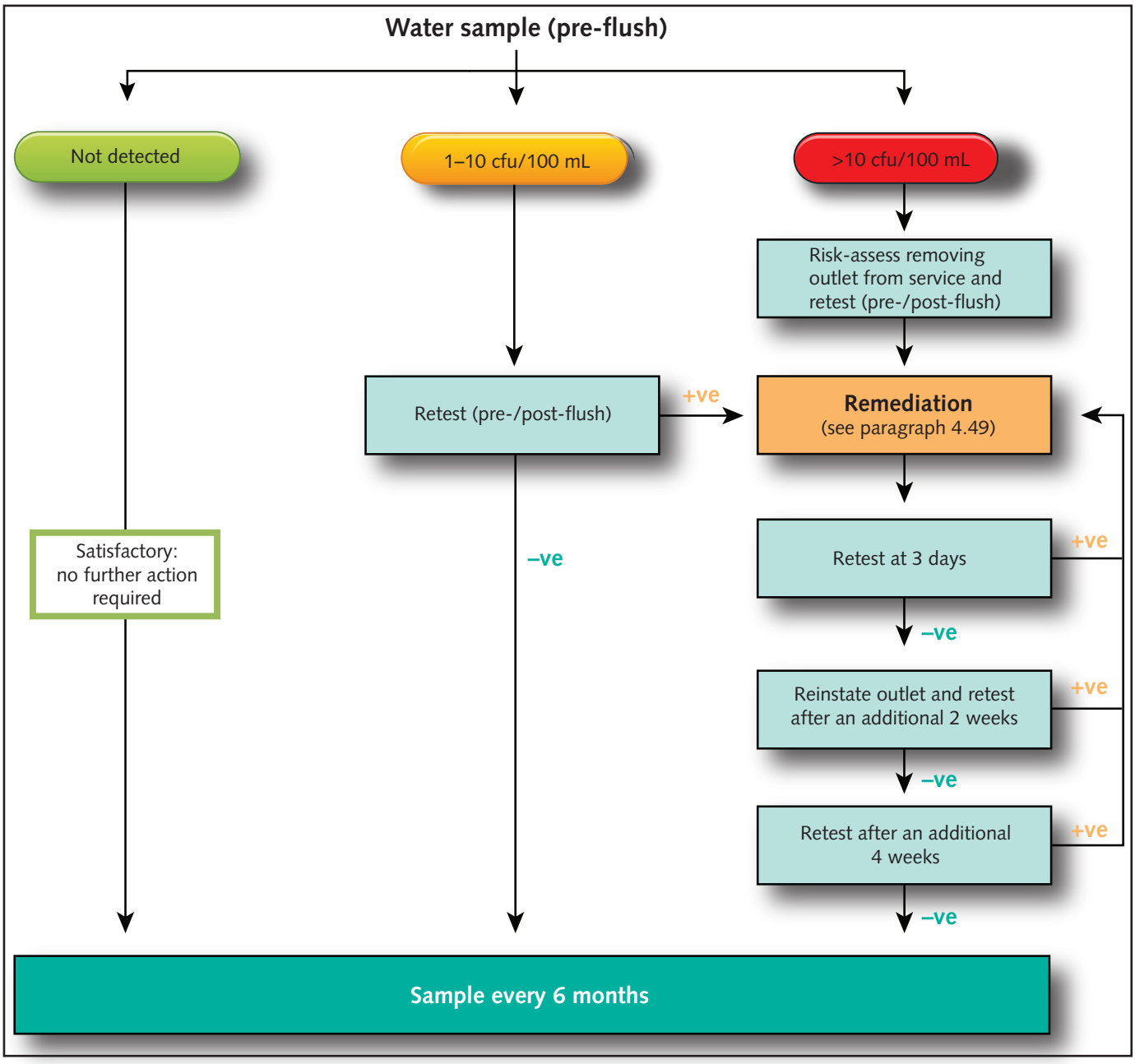
4.44 If test results are not satisfactory (>10 cfu/100 mL), further sampling along with an engineering survey of the water system could be used to identify problem areas and modifications that may be implemented to improve water quality.

4.45 After such interventions, the water should be resampled (see Figure 2 for suggested frequencies).

Note:

Figure 2 gives an example of sampling frequencies. Sampling may be undertaken more frequently according to the risk assessment. It is important that samples are taken as described in Appendix 3 to avoid false negatives.

Figure 2 Summary of suggested water sampling and testing frequencies



Interpretation of pre- and post-flush counts

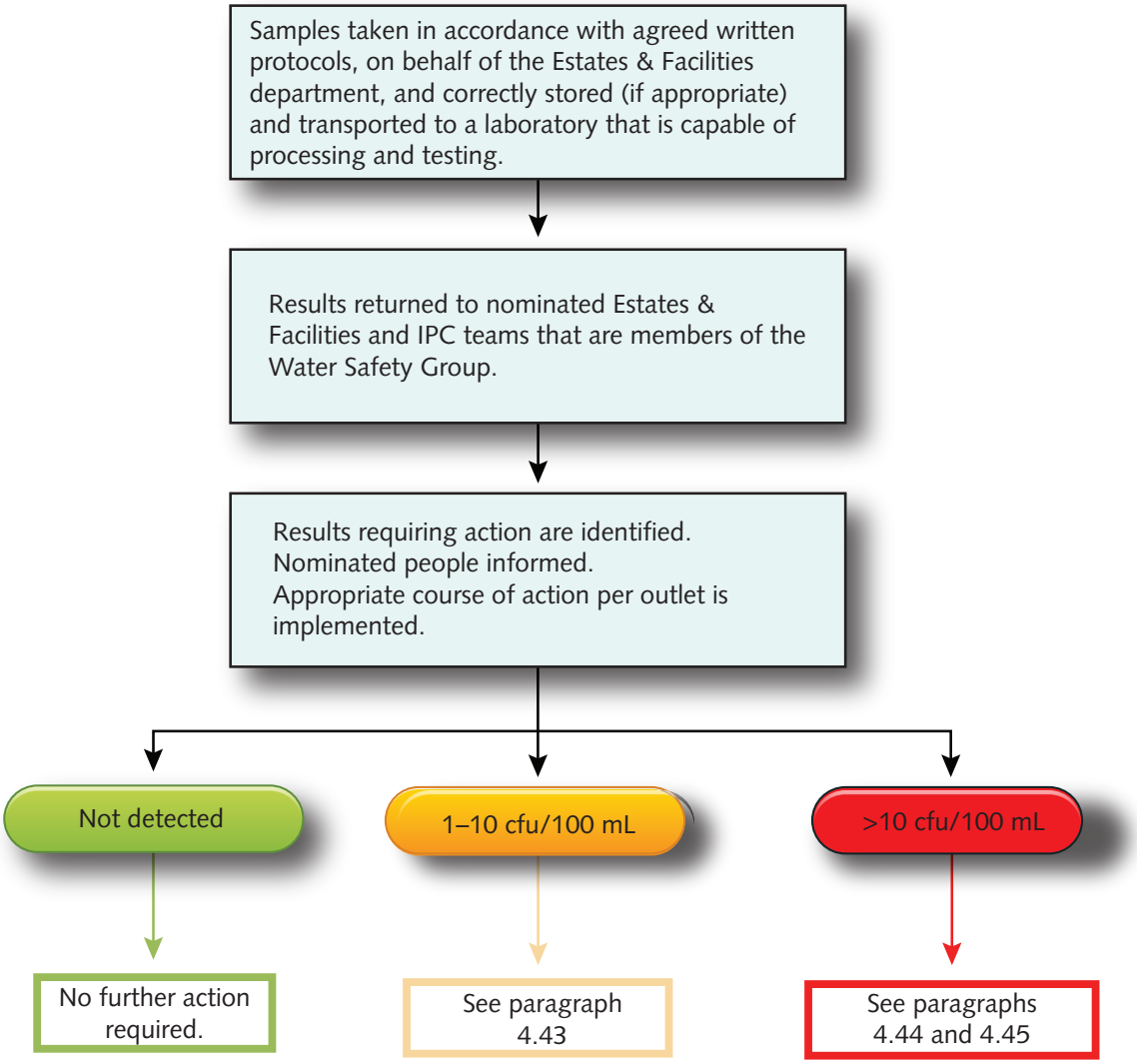
4.46 High counts in pre-flush samples but with low counts or none detected at post-flush could indicate that areas/fittings at or near the outlets are the source of contamination (see Table 1).

- A few positive outlets, where the majority of outlets are negative, would also indicate that the source of contamination is at or close to the outlet.
- If both pre- and post-flush samples from a particular outlet are >100 cfu/100 mL and other

Table 1 Interpretation of pre- and post-flush counts

High *P. aeruginosa* count pre-flush (>10 cfu/100 mL) and low post-flush count (<10 cfu/100 mL)	Suggestive of a local water outlet problem
High *P. aeruginosa* count pre-flush (>10 cfu/100 mL) and high post-flush count (>10 cfu/100 mL)	Suggestive of a problem not related to a local water outlet but to a wider problem within the water supply system

Figure 3 Summary of sampling procedure and interpretation of results for *P. aeruginosa*



nearby outlets have no or low counts, this shows that the single outlet is heavily contaminated, despite the high post-flush count. This could be explored by testing dilutions of pre- and post-flush water samples from this outlet or by using an extended flush such as for 5 minutes prior to post-flush sampling.

Note:

Overlaying sample results onto schematic drawings of the system may help to identify the source of contamination and locations for additional sampling.

4.47 If the sampling indicates that the water services are the problem, then most outlets would possibly be positive and other points in the water system could then be sampled to assess the extent of the problem (see Table 1).

4.48 Figure 3 provides a summary of the sampling procedure and interpretation of results for *P. aeruginosa*.

What to do if a contamination problem is identified

4.49 Should risk assessment or water testing identify contamination with *P. aeruginosa*, the following risk reduction and preventive measures should be considered.

a. If a water outlet has been taken out of service because of contamination with *P. aeruginosa*, continue daily flushing while the outlet is out

of normal use to prevent water stagnation and exacerbation of the contamination.

b. Where practical, consider removal of flow straighteners. However, the removal of flow straighteners may result in splashing and therefore additional remedial action may need to be taken. If they are seen to be needed, periodically remove them and either clean/disinfect or replace them. Replacement frequency should be verified by sampling/swabbing.

c. Splashing can promote dissemination of organisms, resulting in basin outlets becoming heavily contaminated. If splashing is found to be a problem, investigate the causes. Example causes include:

   (i) the tap's designed flow profile is incompatible with the basin;

   (ii) the tap discharges directly into the waste aperture;

   (iii) incorrect height between tap outlet and surface of the basin;

   (iv) excess water pressure;

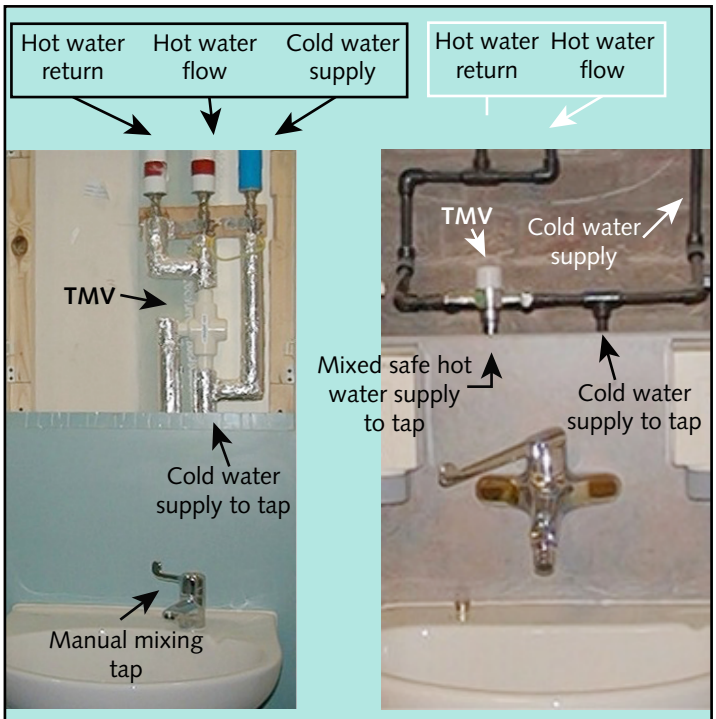
   (v) a blocked or malfunctioning flow straightener.

d. Hand-washing should be supplemented with the use of antimicrobial hand-rub.

e. To prevent water stagnation, check for underused outlets – assess frequency of usage and if necessary remove underused outlet(s). For example, the provision of showers in areas where patients are predominantly confined to bed, and the resultant lack of use, could lead to stagnation.

f. Check connections to mixing taps to ensure that the supply to the hot connection is not supplied from an upstream TMV. In a hot-water service, a dead-leg will exist between the circulating pipework and hot connection of a fitting such as a mixing tap. In the case of cold-water services, sometimes there will be no draw-off from any part of the system and the entire service is in effect a dead-leg. To minimise the stagnation of water in a cold-water system, it can be beneficial to arrange the pipework run so that it ends at a frequently used outlet. A dead-leg may also exist when a TMV is installed upstream of a mixing tap (see Figure 4). Depending on the activities of the room in which the tap is located, cold water may never be drawn through the pipe between the cold water connections of the mixing valve and mixing tap.

Figure 4 Dead-leg formed by the cold pipework when a TMV is installed upstream of a mixing tap



In the case of (a), as the tap lever is moved progressively from left to right, only cold water will be drawn through initially. When fully to the right, cold water will cease to flow and water will flow from the upstream TMV.

In the case of (b), if the lever remains in the fully hot position, as it is raised to draw-off water, there may never be flow from the direct cold-water pipe supplying the tap.

g. Assess the water system for blind ends and dead-legs (for example, where water is supplied to both the cold-water outlet and a TMV supplying an adjacent blended water outlet, as such cold-water outlets in augmented care units may be commonly underused). When removing outlets, the branch hot- and cold-water pipes should also be cut back to the main distribution pipework in order to eliminate blind ends.

h. Assess the water distribution system for non-metallic materials that may be used in items such as inline valves, test points and flexible hoses. They should be replaced according to the guidance in safety alert (DH (2010) 03: 'Flexible water supply hoses'.

i. All materials must be WRAS-approved and must not leach chemicals that provide nutrients that support microbiological growth. Materials should also be compatible with the physical and chemical characteristics of water supplied to the building. Flexible pipes should only be used in exceptional circumstances (for example, where height adjustment is necessary as in installations such as rise-and-fall baths and hand-held showers).

j. POU filters, where they can be fitted, may be used to provide water free of *P. aeruginosa*. Where fitted, regard filters primarily as a temporary measure until a permanent safe engineering solution is developed, although long-term use of such filters may be required in some cases. Where POU filters are fitted to taps, follow the manufacturer's recommendations for renewal and replacement and note that the outer casing of a POU filter and the inner surface can become contaminated (see Health Technical Memorandum 04-01 Part B).

k. In certain circumstances, the WSG may decide it is necessary to carry out a disinfection of the hot- and cold-water distribution systems that supply the unit to ensure that contaminated outlets are treated. See Health Technical Memorandum 04-01 (Part A Chapter 17) for guidance on how to carry out the disinfection procedure. Note that with respect to *P. aeruginosa*, hyperchlorination is not effective against established biofilms. Consider replacing contaminated taps with new taps; however, there is currently a lack of scientific evidence to suggest that this will provide a long-term solution. When replacing taps, consider fitting:

   (i) removable taps;

   (ii) taps that are easy to use;

   (iii) taps that can be readily dismantled for cleaning and disinfection;

   (iv) taps to which a filter can be attached to the spout outlet. Note: Such taps can be used for supplying water for cleaning incubators and other clinical equipment.

Note:

In the event of an outbreak or incident, further advice on the management of *P. aeruginosa* contamination in water systems can be sought from PHE.

Appendix 1 – Best practice advice relating to all clinical wash-hand basins in healthcare facilities

Notes:

1. Clinical wash-hand basins are particularly high risk. It is therefore important to ensure the cleaning of these basins and the taps is undertaken in a way that does not allow cross-contamination from a bacterial source to the tap. During cleaning of basins and taps, there is a risk of contaminating tap outlets with microorganisms if the same cloth is used to clean the bowl of the basin or surrounding area before the tap. Waste-water drain outlets are particularly risky parts of the basin/system and are almost always contaminated (see Breathnach et al. 2012). Bacteria may be of patient origin, so it is possible that bacteria, including antibiotic-resistant organisms, could seed the outlet, become resident in any biofilm and have the potential to be transmitted to other patients.

2. If POU filters are fitted to taps, the same cleaning regimen applies to the wash-hand basin, but clean the filter itself according to the manufacturer's instructions. Take care to avoid contaminating the external surface and outlet of the filter.

Use the clinical wash-hand basin only for hand-washing:

a. Do not dispose of body fluids at the clinical wash-hand basin – use the slophopper or sluice in the dirty utility area.

b. Do not wash any patient equipment in clinical wash-hand basins.

c. Do not use clinical wash-hand basins for storing used equipment awaiting decontamination.

d. Do not touch the spout outlet when washing hands.

e. Clean taps before the rest of the clinical wash-hand basin. Do not transfer contamination from wash-hand basin to wash-hand basin.

f. Do not dispose of used environmental cleaning agents at clinical wash-hand basins.

g. Make sure that reusable containers containing environmental cleaning agents are used in a manner that will protect them from contamination with *P. aeruginosa* (see Aumeran et al. 2007; Ehrenkranz et al, 1980; Sautter et al., 1984).

h. Use non-fillable single-use bottles for antimicrobial hand-rub and soap.

i. Consider the appropriate positioning of soap and antimicrobial hand-rub dispensers. The compounds in the products can be a source of nutrients to some microorganisms. Therefore, it is advisable to prevent soiling of the tap by drips from the dispensers or during the movement of hands from the dispensers to the basin when beginning hand-washing.

j. Identify and report any problems or concerns relating to safety, maintenance and cleanliness of wash-hand basins to the WSG. Escalate unresolved issues to higher management and/or the IPC team as appropriate.

Management should ensure that all staff with responsibility for cleaning should be adequately trained and made aware of the importance of high standards of cleanliness. Refresher training should be given where a specific area does not maintain the expected standard of cleanliness. Visual monitoring of domestic staff should be undertaken by means of regular audits.

Appendix 2 – Types and method of operation of taps and TMVs

Manual mixing taps (non-TMV):

1. There are three main types of manual mixing tap:

- **Single sequential lever operation**. This is the simplest type. As the lever is moved from left to right, or vice-versa, cold water begins to flow and progressively hot water is introduced into the tap body until a fully hot flow is achieved.
- **Single lever combined temperature and flow control**. This type has a lever that may be moved from left to right to control temperature and raised and lowered to control and turn on and off the water flow.
- **Dual lever**. This type has separate lever controls for both the hot and cold water supply to the mixed temperature outlet. As these taps are not normally accessible to patients, the provision of a thermostatic control may be seen as unnecessary.

Note:

The decision whether to install a TMV in areas not normally accessible to patients should be based on a risk assessment (see paragraphs 4.11–4.26). If the risk assessment determines that there is a potential scalding risk, the manual mixing tap should be:

a. preceded by a TMV to ensure that the hot water at the point of discharge is supplied at a safe temperature;

b. a "Type 1" tap, which incorporates a maximum temperature stop to ensure both hot and cold supplies are always flushed.

See Note after paragraph 3.7.

Sensor-operated tap

2. This is essentially an outlet spout of a tap with no manual lever or controls. On/off control of water is by means of a solenoid valve that is activated by an infrared or similar sensor to detect the presence of the user. (Some taps require the metal surface of the spout to be touched.) Water temperature is controlled by a TMV fitted upstream or downstream of the solenoid valve.

Thermostatic mixing tap

3. These are often referred to as mixing taps with integral TMVs. They contain an automatic temperature-controlling device such as a TMV but have an operating mechanism to adjust temperature from fully cold to the maximum pre-set blended water temperature permitted by the automatic device. In the event of failure of the cold water supply, the mixed/blended temperature outlet port will be automatically closed to prevent high water temperature being discharged. The operating mechanism can also control and turn on/off the water flow. They can also be separate mechanisms, functioning independently, with one actuating the flow of mixed water at a fixed temperature and the other actuating the flow of cold water.

Thermostatic mixing valve (TMV)

4. TMVs are typically configured as a t-shaped device with opposing hot and cold water inlets and a mixed/blended temperature water outlet (see paragraph 4.49(f)). They are pre-set to deliver a fixed temperature and, in the event of failure of the cold-water supply pressure, will automatically close to prevent discharge of excessively hot water at the outlet.

Guidance on the selection of taps and basins used in healthcare is given in Health Building Note 00-10 Part C – 'Sanitary assemblies'.

For more information on the TMV approval scheme, visit BuildCert at http://www.buildcert.com/tmv3.htm).

Information on the construction and operation of taps/TMVs used in healthcare can be found on the TMVA website (http://www.tmva.org.uk).

Appendix 3 – Water sampling

1. Sampling should be undertaken by staff trained in the appropriate technique for taking water samples including the use of aseptic technique to minimise extraneous contamination. The method used in this guidance may differ from the collection of water samples for other purposes (for example, for sampling *Legionella*).

2. Carefully label samples such that the outlet can be clearly identified; system schematics indicating each numbered outlet to be sampled can be helpful in this respect.

3. The main strategy for sampling is to take the first sample of water (pre-flush) delivered from a tap at a time of no use (at least 2 hours or preferably longer) or, if that is not possible, during a time of its lowest usage. This will normally mean sampling in the early morning, although a variety of use patterns may need to be taken into account.

4. Disinfectants in the water, such as chlorine or chlorine dioxide, will have residual activity after taking the sample and may inactivate bacteria in the sample prior to its processing. To preserve the microbial content of the sample, neutralise oxidising biocides by dosing the sample bottle with 18 mg of sodium thiosulphate (equating to 18 mg/L in the final sample, which will neutralise up to 50 ppm hypochlorite). Sterile bottles are normally purchased containing the neutraliser. EDTA (ethylenediaminetetraacetic acid) may be used as a neutraliser for systems treated with copper and silver ions (BS 7592). The relevant Health & Safety Executive's advice regarding the use of elemental copper as biocide should be consulted (http://www.hse.gov.uk/legionnaires/faqs.htm#silver-copper-systems). Where disinfectants are being applied to the water system, take advice on the appropriate neutralisers to use.

5. The tap should not be disinfected by heat or chemicals before sampling (pre- or post-flush – see paragraph 12), nor should it be cleaned or disinfected immediately before sampling.

6. Label a sterile collection vessel (200–1000 mL volume) containing a suitable neutraliser for any biocide the water may contain. The labelling information should contain details of the tap location, sender's reference, pre- or post-flush (see paragraph 12), person sampling, date and time of sampling.

7. If *P. aeruginosa* has been found in a pre-flush sample, take a second paired set of samples. The first would be a pre-flush sample as before. Run the tap for two minutes and take a second identical post-flush sample. Bacteria in this second sample (termed post-flush) are more likely to originate further back in the water system. A substantially higher bacterial count in the pre-flush sample, compared with the post-flush, should direct remedial measures towards the tap and associated pipework and fittings near to that outlet. A similar bacterial count in pre-flush and post-flush samples indicates that attention should focus on the whole water supply, storage and distribution system. A more extensive sampling regimen should be considered throughout the water distribution system, particularly if that result is obtained from a number of outlets.

8. Although water sampling is the principal means of sampling, there may be occasions when water samples cannot be obtained immediately for analysis. In the event of a suspected outbreak, swabbing water outlets (as per section 5.4 of the Standing Committee of Analysts' (SCA) 2010 guidance) to obtain strains for typing may provide a means of assessing a water outlet, but this does not replace water sampling (see paragraph 15 on swabbing).

Procedure for obtaining the samples

9. Pre-flush sample: Aseptically (that is, without touching the screw thread, inside of the cap or inside of the collection vessel) collect at least 200 mL water in a sterile collection vessel containing neutraliser. Replace the cap and invert or shake to mix the neutraliser with the collected water.

10. Dependent upon the water distribution system design, and the type of water outlet, the water feed to the outlet may be provided by:

- a separate cold-water supply and hot-water supply to separate outlets;
- a separate cold-water supply and hot-water supply, which may have its final temperature controlled by the use of an integral TMV within the outlet; or

Collect at least 200 mL water in a sterile collection vessel

- a separate cold-water and a pre-blended hot-water supply that has had its temperature reduced by a TMV prior to delivery to the outlet.

11. For separate hot- and cold-water outlets, each outlet is individually tested with its own collection vessel and outlet identifier. For blended outlets (that is, where both hot and cold water come out of the same outlet):

- sample water with the mixing tap set to the fully cold position using an individual collection vessel and outlet identifier, and note the temperature setting;
- sample the blended outlet set to the maximum available hot-water temperature using an individual collection vessel and outlet identifier, and note the temperature setting.

12. Post-flush sample: where this is required, allow the water to flow from the tap for 2 minutes (see above) before collecting at least 200 mL water in a sterile collection vessel with neutraliser. Replace the cap and invert or shake to mix the neutraliser with the collected water. This sample, when taken together with the pre-flush sample, will indicate whether the tap outlet and its associated components is contaminated or if the contamination is remote from the point of delivery (see Table 1).

13. If a sample from a shower is required, then place a sterile bag over the outlet. Using sterile scissors, cut a small section off the corner and collect the sample in a sampling container (see PHE's (2013) 'Guidelines for the collection, microbiological examination and interpretation of results from food, water and environmental samples taken from the healthcare environment' (forthcoming)). Appropriate precautions should be taken to minimise aerosol production as described in BS 7592.

14. The collected water should be processed within 2 hours. If that is not possible, then it should be refrigerated within 2 hours and kept at 2–8°C and processed within 24 hours.

15. To take a swab sample, remove a sterile swab from its container and insert the tip into the nozzle of the tap. Care should be taken to ensure no other surfaces come into contact with the tip of the swab. Rub the swab around – that is, move it backwards and forwards and up and down, as much as possible, on the inside surface of the tap outlet or flow straightener (see photograph). Replace the swab carefully in its container, again ensuring no other surfaces come into contact with the tip of the swab. Place the swab in a transport medium or maximum recovery diluent (MRD) and send to the laboratory.

A sterile swab should be rubbed on the inside surface of the tap outlet or flow straightener

Appendix 4 – Microbiological examination of water samples for *P. aeruginosa*

Notes:

This appendix has been developed to provide technical guidance for a range of laboratories (including NHS, PHE and commercial laboratories) that have the capability and capacity to undertake water sampling and testing.

Alternative water-testing methods other than filtration that can show equivalence and/or improvement on the sensitivity and enumeration of *P. aeruginosa* are also acceptable.

An oxidase test alone is not sufficiently specific to identify *P. aeruginosa.*

Definition

1. *P. aeruginosa* are Gram-negative, oxidase-positive bacteria that, in the context of this method, grow on selective media containing cetrimide (cetyl trimethylammonium bromide), usually produce pyocyanin, fluoresce under ultraviolet light 360 ± 20 nm, and hydrolyse casein. *P. aeruginosa* needs to be identified by the following methods – identification by a positive oxidase test alone is insufficient.

Testing principle

2. A measured volume of the sample or a dilution of the sample is filtered through a membrane filter (≤0.45 microns) to retain bacteria and the filter is then placed on a solid selective and differential medium.

3. CN agar contains **cetyl trimethylammonium bromide** and **nalidixic acid** at concentrations that will inhibit the growth of bacteria other than *P. aeruginosa*. Other selective and differential agars are available and acceptable if validated.

4. The membrane is incubated on a selective/ differential agar and characteristic colonies are counted. Confirmatory tests are carried out where necessary (see paragraph 15) and the result is calculated as the colony count per 100 mL of water.

5. P. aeruginosa usually produces characteristic blue-green or brown colonies when incubated at 37°C for up to 48 hours. Confirmation of isolates is by sub-culture to milk agar supplemented with cetyl trimethylammonium bromide (commercially available) to demonstrate hydrolysis of casein.

Sample preparation and dilutions

6. Water samples should be received and handled as described in the SCAs' 2002 guidance (currently under review). For example, samples should be examined as soon as is practicable on the day of collection. In exceptional circumstances, if there is a delay, store at 2–8°C and do not exceed 24 hours before the commencement of analysis.

Filtration and incubation

7. Aseptically measure and dispense 100 mL of water sample into the sterile filter-holder funnel. If the funnel is graduated to indicate volume, this can also serve to measure the volume.

8. If high bacterial numbers are present in water samples, it may be impossible to count individual colonies accurately on the filter membrane. Therefore, if high counts are expected, a range of dilutions made in sterile diluent (water, MRD or similar) can be processed in parallel with the undiluted sample. An example of this would be a 1-in-10 and a 1-in-100 dilution processed as well as an undiluted sample. Filtration of 10 mL rather than 100 mL is an alternative to filtering 100 mL of a 1-in-10 solution.

9. Draw the water sample through the filter.

10. Aseptically place the membrane onto the pseudomonas selective and differential agar (see paragraph 3) and incubate aerobically at 37°C.

Counting of colonies

11. Examine plates after 22 hours ± 4 hours and 44 hours ± 4 hours of incubation.

12. Count all colonies that produce a green/blue (demonstrating pyocyanin production), or reddish-brown pigment and those which fluoresce under ultraviolet light (optional). Exposure of colonies to daylight for 2–4 hours enhances pigment production. When there is a moderately heavy growth of *P. aeruginosa* and other organisms on the membrane, colonies adjacent to pyocyanin-producing colonies of *P. aeruginosa* can also appear green after 44 hours ± 4 hours of incubation, making the interpretation of the count difficult. Observing the plates after 22 hours ± 4 hours assists in the interpretation in these instances.

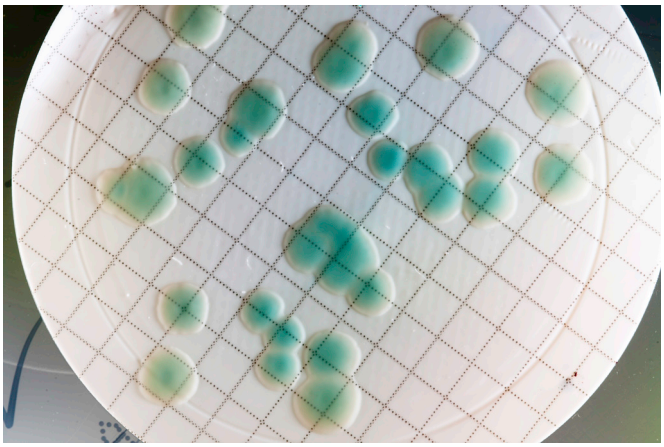


Plate showing high counts of pyocyanin-producing colonies of P. aeruginosa

Processing of swabs

13. Swabs can show presence of *P. aeruginosa* but will not provide equivalent quantitative results as water sampling. They can be used to show the presence or absence of *P. aeruginosa* at the outlet.

14. In the laboratory, use the swab to inoculate a portion of an agar plate that is selective and differential for *P. aeruginosa* (see paragraphs 2 and 3). Streak the inoculum on the plate as for a clinical sample. Incubate as described for filter samples above. Alternatively, after sampling, place the swab in 10 mL MRD, vortex, then plate out (using serial dilution) on the appropriate media and incubate as above.

Confirmatory tests

15. Colonies that clearly produce pyocyanin (green/blue pigmented) on the membrane are considered to be *P. aeruginosa* and require no further testing. Other colonies which fluoresce or are red/brown require confirmation. If more than one volume or dilution has been filtered, proceed if possible with the membrane yielding 20–80 colonies to enable optimum identification and accurate enumeration of colonies. Where there is doubt, perform additional tests to yield reliable species identification.

16. To confirm other colonies, subculture from the membrane onto a milk cetrimide agar (MCA) plate and incubate at 37°C for 22 hours ± 4 hours. Examine the plates for growth, pigment, fluorescence and casein hydrolysis (clearing medium's opacity around the colonies). If pigment production is poor, expose the MCA to daylight at room temperature for 2–4 hours to enhance pigment production and re-examine.

17. *P. aeruginosa* is oxidase-positive, hydrolyses casein and produces pyocyanin and/or fluorescence. Occasionally atypical non-pigmented variants of *P. aeruginosa* occur. A pyocyanin-negative, casein-hydrolysis-positive, fluorescence-positive culture should be regarded as *P. aeruginosa*. Additional tests may be necessary to differentiate non-pigmented *P. aeruginosa* from *P. fluorescens* (such as growth at 42°C or resistance to C-390, 9-chloro-9-(4-diethylaminophenyl)-10-phenylacridan or phenanthroline or more extensive biochemical tests).

Table A1

Colony on CN agar	Oxidase test	Fluorescing on MCA	Caseinolytic on MCA	Confirmed *P. aeruginosa*
Blue or green	+	NT	NT	Yes
Fluorescing and not pigmented	+	+	+	Yes
Reddish brown non-fluorescing	+	+/–	+	Yes
NT = No testing necessary				

Retention of *P. aeruginosa* isolates

18. Where an investigation into clinical infections is underway, inform the testing laboratory that the isolates of *P. aeruginosa* and associated sampling location information should be retained for a minimum of three months as they may be required for typing at a later date.

19. It will then be the responsibility of the testing laboratory to ensure that these isolates are supplied to the typing laboratory (for example, PHE at Colindale) when requested, and this should be written into the contract for testing.

Calculation of results

20. Express the results as colonies of *P. aeruginosa* per 100 mL of the undiluted sample, for example:

- for 100 mL sample – the count on the membrane;
- for 10 mL of sample – the count on the membrane multiplied by 10;
- for 1 mL of sample – the count on the membrane multiplied by 100.

Reporting

21. If *P. aeruginosa* is not detected, report as "Not detected in 100 mL".

22. If the test organism is present, report as the number of *P. aeruginosa* per 100 mL. Reports should be specific to *P. aeruginosa*, and not generic *Pseudomonas* species.

23. The sample reference originally submitted should be reported with each result.

Microbiological typing

24. Water and/or tap-swab isolates being sent to PHE's Antimicrobial Resistance and Healthcare Associated Infections (AMRHAI) Reference Unit for molecular analysis of *P. aeruginosa* should only be referred if the isolates have been confirmed to be *P. aeruginosa* and if there is a possible link to the outbreak strain under investigation.

25. Referrals of *P. aeruginosa* isolates for typing should only be sent after consultation with the typing laboratory.

26. Where many taps are positive for *P. aeruginosa*, send one colony of the *P. aeruginosa* from each water sample. Save the primary isolation plate for possible further examination once the results of typing are known and have been discussed with the typing laboratory. Analysis of results to date has consistently shown that multiple picks have been representatives of the same strain; since multiple taps are being sampled, an idea of the extent of homogeneity or otherwise will still be gained where only one colony is sent from each water sample.

27. If only two or three taps are positive for *P. aeruginosa*, then send two separate colony picks of confirmed *P. aeruginosa* from the primary plate per water sample to AMRHAI (taking the stipulations in paragraph 25 into account). Label these clearly as being from the same water sample (so that AMRHAI can accumulate data on how common mixed strains are seen in the same tap water).

28. It is important that the request forms have information about the links between tap water and cases as illustrated in the following examples:

a. water from tap in room "A" ref patient "X";

b. water from tap in sluice room;

c. tap water from room "C" with no cases.

29. It is important to recognise that there are some types of *P. aeruginosa* that are relatively commonly found in the environment and among patient samples globally. These include the PA14 clone and clone C; a match between patient and water samples with these strains is not necessarily evidence of transmission between the two.

Flowchart showing the processing and enumeration of *P. aeruginosa* by membrane filtration

Appendix 5 – Example of a typical risk assessment to inform the WSP for augmented care units

Facility/ward/department: _____ Assessment completed by: _____

Date: _____ _____

Brief description of activity, location or equipment: to determine the level of risk that *Pseudomonas aeruginosa* from the water use/supply poses to the patients in the unit

Description of the hazards	Persons affected by the work activity and how	Existing controls	Likelihood	Impact	Risk rating
Infection/colonisation with Pseudomonas aeruginosa from contaminated water (Names/titles):	Susceptible patients within augmented care units **Note to reader**: This is an example risk assessment. The control measures outlined are not exhaustive but are for illustrative purposes only. Each healthcare provider will have its own risks and will need to carry out a risk assessment based on these risks (see paragraphs 4.18-4.23 for examples of other risks and further guidance).	USE OF WATER: For direct contact with patients, water of a known satisfactory quality is used: • water where testing has shown absence of P. aeruginosa; or • water supplied through a point-of-use (POU) filter; or • sterile water (for skin contact for babies in neonatal intensive care units). ENGINEERING ASSESSMENT OF WATER SYSTEMS: • Correct installation and commissioning of water systems in in line with HTM 04-01 is adhered to • Schematic drawings are available for water systems. FLUSHING: • Flushing of water outlets is carried out and documented. SAMPLING: • Plans for the sampling and microbiological testing of water are in place			(See risk scoring matrix on next page)

Risk scoring matrix

Risk scoring: Use the grid below to achieve and overall score for the risk by measuring across for the impact and down for the likelihood.

		IMPACT				
		1	2	3	4	5
LIKELIHOOD	1	1	2	3	4	5
	2	2	4	6	8	10
	3	3	6	9	12	15
	4	4	8	12	16	20
	5	5	10	15	20	25

Key	Green Low	Amber Medium	Red High

The resulting **action plan** should include:

- Sources of information/persons consulted
- Further action if necessary to control the risk
- Person/s responsible for coordinating implementation of the action.
- Recommended timescales
- Date completed
- Revised risk rating

Appendix 6 – Exemplar *P. aeruginosa* sample sheet

Hospital/site: St Lukes	Time sample taken: 07.00
Building: East Wing	Date: 20 February 2013
Faculty/department/ward: 12	Name of sampler (print): J. JONES

Bacterial species:
Pseudomonas aeruginosa

Note: The tap should not be cleaned or disinfected by heat or chemicals immediately before sampling

Room No.	Room name	Outlet type	Outlet ID No.	Pre-flush sample	Post-flush sample	Sample's barcode (affix adjacent to sample details)
101	Neonatal ICU:					
	-WHB	-Mixer	-001	Yes		
	-WHB	-Mixer	-002	Yes	Yes	
102	Neonatal ICU clean utility:					
	-WHB	-Mixer	-003	Yes		
	-Sink	-H/C lever-op	-004	Yes		

Notes

Refer to Appendix 3 in HTM 04-01 'Addendum: *Pseudomonas aeruginosa* **– advice for augmented care units' for detailed advice on obtaining samples correctly**

References

Acts and regulations

Health and Safety at Work etc. Act 1974.
http://www.legislation.gov.uk/ukpga/1974/37

Water Supply (Water Fittings) Regulations 1999.
http://www.legislation.gov.uk/uksi/1999/1148/contents/made

Water Supply (Water Quality) Regulations 2000 (as amended).
http://www.legislation.gov.uk/uksi/2000/3184/contents/made

British Standards

BS 7592. Sampling for Legionella bacteria in water systems. Code of practice. British Standards Institution, 2008.
http://shop.bsigroup.com/en/ProductDetail/?pid=000000000030161148

DH estates and facilities guidance

Note:

The Space for Health website is closing. From April 2013, all DH estates guidance and other materials normally accessed via Space for Health will be available from the individual websites of England, Wales, Scotland and Northern Ireland.

As the details of these individual websites are not currently available, any queries about the status of, and access to, the following DH estates guidance documents should be addressed to help@spaceforhealth.net

This reference list will be updated once the full access details of the migrated guidance documents are established.

Estates and facilities alert notices

DH (2010) 03. Flexible water supply hoses. 2010.
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_115847.pdf

Health Building Notes

Health Building Note 00-09. Infection control in the built environment. 2013.

Health Building Note 00-10 Part C. Sanitary assemblies. 2013.

Health Technical Memoranda

Health Technical Memorandum 04-01 Part A. The control of Legionella, hygiene, "safe" hot water, cold water and drinking water systems: design, installation and testing. 2006.

Health Technical Memorandum 04-01 Part B. The control of Legionella, hygiene, "safe" hot water, cold water and drinking water systems: operational management. 2006.

Other DH publications

(The) Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance. 2010.
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_122604

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Breathnach, A.S., Cubbon, M.D., Karunaharan, R.N., Pope, C.F. and Planche, T.D. (2012). **Multidrug-resistant Pseudomonas aeruginosa outbreaks in two hospitals: association with contaminated hospital waste-water systems**. *Journal of Hospital Infection*. September. Vol. 82 No. 1, pp. 19–24.

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Ehrenkranz, N.J., Bolyard, E.A., Wiener, M. and Cleary, T.J. (1980). **Antibiotic-sensitive Serratia marcescens infections complicating cardiopulmonary operations: contaminated disinfectant as a reservoir**. *Lancet*. Vol. 2 No. 8207, pp. 1289–92.

Health & Safety Executive (2000). **Legionnaire's disease: the control of legionella bacteria in water systems – Approved Code of Practice and guidance**. http://www.hse.gov.uk/pubns/priced/l8.pdf

PHE (Public Health England) (2013). **Guidelines for the collection, microbiological examination and interpretation of results from food, water and environmental samples taken from the health care environment** (forthcoming).

Pratt, R.J., Pellowe, C.M., Wilson, J.A., Loveday, H.P. et al. (2007) **epic2: National evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England**. *Journal of Hospital Infection*. Vol. 65 (Supplement). http://download.journals.elsevierhealth.com/pdfs/journals/0195-6701/PIIS0195670107600024.pdf

Sautter, R.L., Mattman, L.H. and Legaspi, R.C. (1984). **Serratia marcescens meningitis associated with a contaminated benzalkonium chloride solution**. *Infection Control*. Vol. 5 No. 5, pp. 223–225.

Standing Committee of Analysts (2002). **The microbiology of drinking water. Part 3 – Practices and procedures for laboratories: methods for the examination of waters and associated materials**. Environment Agency (currently under review). http://www.environment-agency.gov.uk/static/documents/Research/mdwpart3.pdf

Standing Committee of Analysts (2010). **The microbiology of drinking water. Part 2 – Practices and procedures for sampling: methods for the examination of waters and associated materials**. Environment Agency. http://www.environment-agency.gov.uk/static/documents/Research/MoDW-2-232.pdf

WHO (World Health Organization) (2011). **Water safety in buildings**. WHO, Geneva. http://www.who.int/water_sanitation_health/publications/2011/9789241548106/en/

SAFETY ACTION NOTICE

ESTATES AND FACILITIES EQUIPMENT

SAN(SC)09/03
30 NOV 2009
Facilities
Page 1 of 2 Pages

Flexible water supply hoses: risk of harmful micro-organisms

SUMMARY

When used for the supply of potable water, flexible hoses may have an enhanced risk of harbouring *Legionella* bacteria and other potentially harmful micro-organisms. Advice is provided on risk control measures.

BACKGROUND

1. Flexible hoses (also known as 'tails') are often used in the supply of water to equipment such as baths, wash hand basins, showers, ice making machines, dish / glass washers, drink vending machines, drinking fountains, endoscope washers, clothes washing machines and wash down hoses (please note that this list is not exhaustive). They may also be connected to system components such as pressure reducing valves, non-return valves, strainers, thermostatic mixing valves and shower mixers.

2. Flexible hoses may be used to link between hard pipework and equipment, often for convenience rather than being necessary. They are typically steel braided with a synthetic rubber inner lining such as EPDM (ethylene propylene diene monomer).

3. HFS has received reports that high levels of *Pseudomonas* and *Legionella* bacteria have been found in water samples taken from water outlets fed by flexible hoses, confirmed by testing of the hoses which revealed colonisation of the lining. The lining material in these reports was EPDM. However, it is possible that other lining materials (and washers within the couplings) could be similarly affected.

4. New lining materials such as PE (polyethylene), PEX (cross-linked polyethylene), LLDPE (linear low density polyethylene) and PVC C (post chlorinated PVC) are now on the market and others are likely to follow. However, their long term performance regarding the growth of micro-organisms is still unknown. Changes in this situation may be reflected in future guidance such as SHTM 04-01[(1)].

5. This notice applies to flexible hoses from mixed water supplies as well as to separate hot and cold water systems and feeds. This notice is **not** concerned with primary heating circuits, sealed chilled water systems or shower hoses (between mixer and shower head).

ACTION

6. This notice should be brought to the attention of all appropriate managers and staff, and in particular to capital planning / estates / facilities managers and their design teams and contractors.

Suggested Distribution	Accommodation Officers	Capital Planning & Design	Care Home Services
Catering	Community Care	Estates/Facilities	Health & Safety
Hospices	Infection Control Staff	Microbiology	Public Health
Respiratory Medicine	Risk Management		

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A Division of NHS National Services Scotland

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SAFETY ACTION NOTICE

ESTATES AND FACILITIES EQUIPMENT

NHS National Services Scotland

Flexible water supply hoses: risk of harmful micro-organisms

7. Flexible hoses used in potable water supply systems should be identified and risk assessed for the possibility of contamination with harmful micro-organisms.

8. An action plan should be developed by each Board which gives priority to areas of highest risk (i.e. those with persons vulnerable to infection). Depending on the risk assessment, the action plan should address replacement of flexible hoses with hard or soft bendable metal or plastic pipes.

9. Where flexible hoses must be used (e.g. on essential equipment such as hi-low baths) they must be lined with a suitable alternative to EPDM, as well as being WRAS approved. Care should be taken to avoid kinking or distorting them during installation.

10. Risk assessments should be reviewed regularly and whenever there are changes to the patient user group or alterations made to the potable water system.

11. Enquiries regarding specific types of flexible hose should be directed to the manufacturer/supplier.

REFERENCES

(1) Scottish Health Technical Memorandum SHTM 04-01: *The control of Legionella, hygiene, 'safe' hot water, cold water and drinking water systems* (working draft due for publication January 2010; SHTM 2027 and 2040 will be withdrawn)

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Dr J Rogers, et al. (1994) *Influence of plumbing materials on biofilm formation and growth of Legionella pneumophila in potable water systems,* Applied and Environmental Microbiology, Volume 60, No. 6, p1842-51

SCOTTISH HOSPITALS INQUIRY

Bundle of documents for Oral hearings commencing from 19 August 2024 in relation to the Queen Elizabeth University Hospital and the Royal Hospital for Children, Glasgow

Bundle 44 – Volume 4

Report by Dr Chaput and Dr Mumford, and miscellaneous documents