

The Regulation and Quality Improvement Authority

Independent Review of Incidents of *Pseudomonas* aeruginosa Infection in Neonatal Units in Northern Ireland

Final Report

31 May 2012

The Regulation and Quality Improvement Authority

The Regulation and Quality Improvement Authority (RQIA) is the independent body responsible for regulating and inspecting the quality and availability of health and social care services in Northern Ireland.

RQIA was established in 2005 as a non-departmental public body under The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 to drive continuous improvements in the quality of services, through a programme of inspections and reviews.

The vision of RQIA is to be a driving force for positive change in health and social care services in Northern Ireland.

This is accomplished by focusing on the delivery of a robust quality and regulatory framework which is fit for purpose. This ensures that RQIA provides independent assurance about the safety, quality and availability of health and social care services in Northern Ireland; encourages continuous improvements in those services; and safeguards the rights of service users. This is undertaken through four outcomes:

- Improving care: we encourage and promote improvements in the safety and quality of services through the regulation and review of health and social care
- Informing the population: we publicly report on the safety, quality and availability
 of health and social care
- Safeguarding rights: we act to protect the rights of all people using health and social care services
- Influencing policy: we influence policy and standards in health and social care

RQIA encourages continuous improvement in the quality of services, through a planned programme of inspections and reviews.

The RQIA Review Programme takes into consideration relevant standards and guidelines, the views of the public, health care experts and current research.

During these reviews we examine the service provided, highlight areas of good practice and make recommendations for improvements to the service provider. We report our findings and share any lessons learned across the wider health and social care sector.

In addition, when required, we carry out reviews and investigations in response to specific issues of concern or failures in service provision.

The outbreaks and incidents of *Pseudomonas aeruginosa* which occurred across Northern Ireland during December 2011 and January 2012 have resulted in this review, facilitated by RQIA, which was undertaken in response to a request by the Minister for Health and Social Services and Public Safety.

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Final Report

Foreword by Professor Pat Troop

Independent Review of Incidents of *Pseudomonas aeruginosa* Infection in Neonatal Units in Northern Ireland

I have been privileged to lead this RQIA independent review which was commissioned by the Minister for Health, Social Services and Public Safety following the serous outbreak and tragic deaths of babies from Pseudomonas. I am also very grateful to the expert members of the review team who have given their time willingly in this very important piece of work.

This review was initiated very quickly after the events of December and January. This ensured that they were still fresh in the minds of those involved and that documents were readily available, so we are confident we have been able to put together an accurate picture of those events. Our broad terms of reference also enabled us to look not just directly at the events themselves, but at many issues around them. This detailed wider examination does not often happen after outbreaks, and it has enabled us to learn many valuable lessons which have wider significance.

When we started to meet with organisations, staff and parents, we were told that they wanted to make sure that we learned from what had happened and make improvements. The parents in particular told us that they did not want other parents to have the same experience as them. We have been impressed by the openness and honesty of all those involved. We have asked for large volumes of information and documentation, held many meetings and we have been given full cooperation at all stages.

In the interim report, we identified a number of concerns and areas for improvement. A series of recommendations was made, designed to have an immediate effect on the safety and effectiveness of the neonatal system in Northern Ireland. The review team was very pleased that all recommendations were accepted by the Minister for Health and are in the process of being implemented. We are also aware the interim report and its recommendations influenced the development of UK wide guidance.

As part of the second phase of the review we have met with senior teams from all of the organisations involved and we have been told that they have used the review as an opportunity to reflect on and strengthen their systems. We have now made a number of further recommendations, particularly in communications. Sadly, in serious events, communication is often one of the casualties. Therefore our recommendations are on making these more systematic, relying less on informal networks, and ensuring that information is shared and reaches those that need it.

In the interim report we drew attention to potential risks from contamination of taps. We have now received a report from the Health Protection Agency who have looked at the taps from the Neonatal Units in Northern Ireland, demonstrating a clear link between pseudomonas and specific components of taps. I believe this could lead to a genuine improvement in tap design to improve patient safety.

Finally, I would like to take this opportunity to thank all families who engaged with the review team. What they told us made a major contribution to our understanding of events, but hearing their stories also helped us to keep their needs at the centre of considerations.

We were impressed by the dignity and honesty of those families and by the fact that key motivation for coming forward was to try to ensure that such a tragic incident does not happen again.

Pat Toop.

Professor Pat Troop CBE FRCP FFPH DSc

Review Chair

Table of Contents

Foreword by Professor Pat Troop

1.	introduction and Background to Phase Two of the Review			
3.	Terms of Reference Methodology			
				3.1
		3.2	Information Requests	4
	3.3	Interviews and Meetings: Phase One	5	
	3.4	Interviews and Meetings: Phase Two	6	
	3.5	Engagement with Families	6	
4.	Summary of Findings from Phase One			
	4.1	Outbreaks and Incidents of Pseudomonas aeruginosa linked to Neonat	tal	
		Units	7	
	4.2	Findings in Relation to the First Term of Reference	8	
	4.3	Findings in Relation to the Second Term of Reference	9	
	4.4	Actions Taken Since the Publication of the RQIA Interim Report	10	
5.	The Experience of Families			
	5.1	Introduction	12	
	5.2	Feelings of the Families	13	
	5.3	Communication	14	
	5.4	Impressions of the Neonatal Units	16	
	5.5	What Could Have Been Done Better	17	
	5.6	Conclusion	17	
6.	Governance Arrangements			
	6.1	Introduction	19	
	6.2	Governance Arrangements for Ensuring Appropriate Action is Taken in	1	
		Response to Circulars and Advices	19	
	6.3	Governance Arrangements in Relation to the Management of Water		
		Distribution Systems	20	

6. Governance Arrangements (Continued)

	6.4	Response to Relevant Circulars and Advices issued from September 2010 to			
		January 2012 in Respect of Water Sources and Potential Infection Risk to			
		Patients	24		
	6.5	Governance Arrangements in Relation to the Prevention and Control of			
		Infection	35		
	6.6	Governance Arrangements in Relation to the Reporting and Follow-up of			
		Incidents	40		
	6.7	Recommendations in Relation to Governance	41		
7.	Con	nunication			
	7.1	Introduction	42		
	7.2	Effectiveness of the General Arrangements for the Communication of			
		Information about Infectious Diseases within Northern Ireland	42		
	7.3	Effectiveness of the Communication between Organisations about the			
		Outbreaks and Incidents of Pseudomonas from December 2011 up to the			
		Declaration of an Outbreak at Royal Jubilee Maternity Service Neonatal Uni	t		
		on 17 January 2012	46		
	7.4	Effectiveness of the Communication and the Co-ordination of Arrangements	;		
		between Organisations following the Declaration of an Outbreak at Royal Ju	ıbilee		
		Maternity Service Neonatal Unit on 17 January 2012 up to			
		31 January 2012	51		
	7.5	Recommendations in Relation to Communication	54		
8.	Find	lings in Relation to Other Matters	55		
	8.1	The Impact on Staff	55		
	8.2	Use of Sterile Water for Washing Babies	55		
	8.3	Update on Other Investigations and Processes	56		
	8.4	Recommendations	58		
9.	Ove	rall Conclusions from the Review	59		
_	9.1	To Investigate the Circumstances Contributing to the Occurrence of			
		Pseudomonas Infection in Neonatal Units from 1 November 2011	59		
	9.2	To review the effectiveness of the trusts' management of the occurrences of			
		pseudomonas infection and colonisation within neonatal units	60		

9. Overall Conclusions from the Review (Continued)

	В	Circular HSS(MD)15/2012 issued on 6 April 2012	73	
	Α	Recommendations from Phase One	71	
	Appendices			
11.	Glos	sary of Terms and Abbreviations	70	
10.	Sum	mary of Recommendations from Phase Two	68	
	9.7	To identify any learning and make recommendations for all organisations involved	67	
	9.6	To consider the experience of families of babies affected by the pseudomor infection and colonisation within neonatal units since1 November 2011	nas 66	
	9.5	To examine any other relevant matters which emerge during the course of t review	the 65	
	9.4	To review the effectiveness of the communication between the DHSSPS, the HSCB, the PHA, and the five health and social care trusts in respect of all relevant information and communications on the pseudomonas bacterium	ne 63	
	9.3	To review the effectiveness of the governance arrangements across all five health and social care trusts with regard to the arrangements for the prever and control of infection and all other relevant issues in their respective neor units	ntion natal 61	

1. Introduction and Background to Phase Two of the Review

On 12 December 2011 the Western Health and Social Care Trust (Western Trust) declared an outbreak of *Pseudomonas aeruginosa* at the neonatal unit at Altnagelvin Hospital, Londonderry, after three babies were confirmed to be infected. One baby had tragically died and a second baby had been transferred to the regional neonatal unit in the Royal Jubilee Maternity Service (RJMS). The third baby continued to be cared for in Altnagelvin at that time.

On 17 January 2012 the Belfast Health and Social Care Trust (Belfast Trust) declared an outbreak of *Pseudomonas aeruginosa* in the RJMS regional neonatal unit. At that time two babies who had been confirmed as having the infection had tragically died and another baby was known to have been infected. A third baby sadly died after the outbreak was declared.

Subsequently information became available through typing of strains of pseudomonas that one of the babies who had died in Belfast had a strain of pseudomonas which has been linked to Craigavon neonatal unit. It was also found that a baby, who had been diagnosed with pseudomonas at Craigavon Hospital in December 2011, had the strain of pseudomonas which caused the outbreak in Belfast. This baby sadly died in January 2012. Pseudomonas was not the reported cause of death.

During the period from 17 to 31 January 2012, screening of babies in units across Northern Ireland confirmed that there were babies in other units who had been colonised with pseudomonas on their skin.

On 30 January 2012, Mr Edwin Poots, the Minister for Health, Social Services and Public Safety, asked RQIA to facilitate the establishment of an independent review into the circumstances leading to the incidents and the effectiveness of the response. The review should also examine the experience of the families of the babies who had died and of others who had been affected by the incidents. Terms of reference were agreed and RQIA established the review team under the chairmanship of Professor Pat Troop.

An interim report was submitted to the Minister on 30 March 2012 and published on 4 April 2012. A summary of the interim findings is provided in Section 4 of this report. This report does not replicate the full detail of the interim report which is available on the RQIA website. The interim report made 15 recommendations which are set out in Appendix A.

This report sets out the findings and conclusions of the review team in relation to those terms of reference not addressed in the interim report. In particular, it focuses on the experiences of nine families who met with members of the review team.

We are very grateful to all the parents and grandparents who met with us at a very difficult time for them. We also thank the members of staff of all organisations who facilitated the review team throughout both phases of this review.

2. Terms of Reference

The terms of reference for the review were agreed with the Minister for Health, Social Services and Public Safety and the Chair of the RQIA Independent Review Team.

It was agreed that the review would focus on the occurrences of *Pseudomonas aeruginosa* which led to the tragic deaths of a baby in Altnagelvin Hospital and three babies in the Royal Jubilee Maternity Hospital's neonatal intensive care unit.

The review would also examine the actions and responses of eight organisations to relevant circulars and advices issued in respect of water sources and potential infection risk to patients, disseminated since 15 September 2010. The organisations reviewed were:

- Department of Health, Social Services and Public Safety (DHSSPS)
- Health and Social Care Board (HSCB)
- Public Health Agency (PHA)
- Belfast Health and Social Care Trust (Belfast Trust)
- Northern Health and Social Care Trust (Northern Trust)
- South Eastern Health and Social Care Trust (South Eastern Trust)
- Southern Health and Social Care Trust (Southern Trust)
- Western Health and Social Care Trust (Western Trust)

The review was commissioned under Article 35(1) (b) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 and covered the period 1 November 2011 to 31 January 2012.

The review was conducted in two phases.

Phase One Terms of Reference

- 1. To investigate the circumstances contributing to the occurrences of pseudomonas infection in neonatal units from 1 November 2011.
- 2. To review the effectiveness of the trusts' management of the occurrences of pseudomonas infection and colonisation within neonatal units, to include:
 - a. The management of the occurrence of pseudomonas infection and colonisation in the neonatal unit in the Western Trust.
 - b. The management of the declared outbreak of pseudomonas infection and colonisation in the neonatal unit in the Belfast Trust in January 2012.
 - c. The management of any colonised babies in the other neonatal units across Northern Ireland.
- 3. To review the effectiveness of the governance arrangements across all five health and social care trusts with regard to the arrangements for the prevention and control of infection and all other relevant issues in their respective neonatal units.

- 4. To review the effectiveness of the communication between the DHSSPS, the HSCB, the PHA, and the five health and social care trusts in respect of all relevant information and communications on the pseudomonas bacterium.
- 5. To examine any other relevant matters which emerge during the course of the review.
- 6. To identify any learning from the circumstances and make recommendations for all agencies involved.

Phase Two Terms of Reference

In recognition of the tragic impact of pseudomonas infection for the families of those babies who have been directly affected by the bacterium, RQIA during the course of this review will engage directly with the parents of those babies affected. Phase two of the review will deal directly with these issues. Early into the review, it was agreed that families may wish to come forward as soon as possible and thus the opportunity was afforded to those families to meet with the review team prior to phase one being concluded. RQIA believes that this is a vital part of the review to ensure the stories of families are told and therefore this invitation was extended to the beginning of May 2012.

- 1. To consider the experience of families of babies affected by the pseudomonas infection and colonisation within neonatal units since 1 November 2011.
- 2. To examine any other relevant matters which emerge during the course of phase two of the review.
- 3. To identify any learning from the experiences of parents and make recommendations for all organisations involved.

Arrangements for Reporting

The Minister for Health, Social Services and Public Safety requested two reports to be completed:

An interim report to be completed by the end of March 2012 which would highlight the key findings and provide recommendations which should be implemented immediately to assure the safety of the neonatal service. This report was published on the RQIA website on 4 April 2012 and made 15 recommendations for action.

A final report to be completed by the end of May 2012 which would provide further detail and recommendations for the service.

The full details of the interim report are not included in this final report. The interim report can be accessed on the RQIA website.

3. Methodology

3.1 The Independent Review Team

The review was conducted by an independent review team established at the beginning of February 2012. Its membership included:

- Professor Pat Troop, CBE, former Chief Executive of the Health Protection Agency, former Deputy Chief Medical Officer at the Department of Health (England) (Chair of the RQIA Independent Review Team)
- Mr Andy Cole, Chief Executive from the charity, Bliss (Babies born too soon, too small, too sick)
- Dr Michael Kelsey, Consultant Microbiologist, Whittington Hospital NHS Trust, London
- Dr Ian Laing, former Consultant Neonatologist and Clinical Lead for the Neonatal Managed Clinical Network of the South and East of Scotland
- Ms Ann McMurray, lay reviewer from the charity, Sands (Stillbirth and Neonatal Death)
- Mr Graham Marsh, former NHS Acute Foundation Trust Director of Property and Medical Engineering
- Ms Mae Nugent, Practice Development Nurse, Neonatal Unit, University College London Hospital NHS Foundation Trust, London
- Dr Tyrone Pitt, former Deputy Director of the Laboratory of HealthCare Associated Infections (LHCAI), Health Protection Agency, London and Bacteriology Consultant to the National Health Service Blood and Transplant Service
- Ms Farrah Pradhan, lay reviewer from the charity, Bliss (Babies born too soon, too small, too sick)
- Dr David Stewart, Director of Reviews and Medical Director, RQIA

The independent review team was supported by RQIA staff:

- Ms Janine Campbell, Project Administrator
- Mrs Elizabeth Colgan, Senior Inspector, Infection Prevention/Hygiene
- Mr Hall Graham, Head of Primary Care and Reviews
- Mrs Jacqueline Murphy, Senior Project Manager

3.2 Information Requests

RQIA wrote to those organisations subject to the review to request their co-operation in informing the review. Detailed information was requested from them, including:

A chronology of the events relating to the organisation which was relevant to the review's terms of reference. This chronology covered the period from 15 September 2010 (date of issue of DHSSPS Circular HSS (MD)34/2010: Water Sources and Potential Cross Infection Risks from Taps and Basins – Interim Advice) until 31 January 2012 (date of Minister's statement to the NI Assembly, announcing the commencement of the review).

Details of all actions taken following the DHSSPS letters:

- DHSSPS Letter: HSS(MD)34/2010 from Chief Medical Officer and Deputy Secretary/Chief Estates Officer, dated 15 September 2010: Water Sources and Potential Cross Infection Risks from Taps and Basins – Interim Advice
- 2. DHSSPS Letter: PEL(11)13 from Deputy Secretary/Chief Estates Officer, dated 1 July 2011: Water Systems and Potential Infection Risks
- 3. DHSSPS Letter HSS(MD)31/2011 from Chief Medical Officer and Deputy Secretary/Chief Estates Officer, dated 22 December 2011: Water Sources and Potential Infection Risk to Patients
- 4. DHSSPS Letter HSS(MD)4/2012 from Chief Medical Officer and Deputy Secretary/Chief Estates Officer, dated 28 January 2012: Interim Guidance on Pseudomonas and Neonatal Units

Description of organisational structures, to include:

- senior management structure
- lead responsibility and groups relevant to the planning or provision of neonatology services
- lead responsibility and groups relevant to infection control
- lead responsibility and groups relevant to estates services

Copies of all relevant policies and procedures.

Copies of all **relevant documentation** (to include minutes of meetings and correspondence) with regard to the chronology of events.

Copies of all **relevant governance documentation** (eg: incidents reporting, risk registers, etc) with regard to the chronology of events.

Details of any other relevant information surrounding the pseudomonas outbreaks from 1 November 2011 until 31 January 2012.

Each HSC trust was also requested to complete a questionnaire outlining the **profile of** the neonatal units and special care baby units (SCBUs) and to submit copies of results of microbiological investigations of water or clinical samples for pseudomonas linked to each neonatology unit/special care baby unit.

Further requests for information have been made as the review has progressed.

3.3 Interviews and Meetings: Phase One

Visits to the five Neonatal Intensive Care Units (NICUs) in Northern Ireland were undertaken by members of the independent review team who met with various levels of staff, including medical and nursing staff.

Also during a four week period, meetings and interviews were held with managerial and clinical staff across the health and social care sector.

During phase one, liaison with national organisations, including the Health Protection Agency (HPA), also took place to ensure a comprehensive understanding of the situation across the United Kingdom.

3.4 Interviews and Meetings: Phase Two

During phase two of the review, the review team sought and were provided with clarification on a number of issues outstanding from phase one. The extensive body of evidence provided was reviewed in relation to the terms of reference considered in this report.

Members of the review team held further meetings with senior representatives of each organisation subject to the review to consider issues relating to governance and communication. Trust representation included non-executive members of the Trust Board to facilitate discussions on Board involvement in trust governance processes.

3.5 Engagement with Families

During phase one of the review the parents of children affected by the incidents of pseudomonas were contacted on behalf of the review team. They were invited to meet with team members to share their experience. Nine families came forward and over the course of the review met with the team in response to these invitations.

4. Summary of Findings from Phase One

4.1 Outbreaks and Incidents of *Pseudomonas aeruginosa* linked to Neonatal Units

The review team found that four of the five major neonatal units in Northern Ireland had outbreaks or incidents of *Pseudomonas aeruginosa* between November 2011 and January 2012. From epidemiological analysis carried out by the PHA and typing of bacteria carried out by the HPA, the review team was advised that the strain or strains of pseudomonas linked to each unit were different which indicated that these were separate outbreaks or incidents. There was no evidence of direct spread of the bacteria between different units.

Altnagelvin Hospital

An outbreak of infection caused by *Pseudomonas aeruginosa* was declared at Altnagelvin Neonatal Unit on 12 December 2011. This caused infection between 26 November 2011 and 10 December 2011 of three very pre-term babies, one of whom died. All three babies had been nursed in the Intensive Care Unit (ICU) room of the Neonatal Intensive Care Unit (NICU).

Two babies had the same strain of *Pseudomonas aeruginosa* as was found in a contaminated tap at the back of the ICU room. The other baby had a different strain which was subsequently found from a swab of a sink at the front of the ICU room on 12 January 2012. This sink had previously tested as negative.

Following a programme of actions to control the outbreak, there were no further cases of infection in the unit after 10 December 2011. In January 2012, through a weekly screening programme established following the outbreak, two babies were found to have colonisation with *Pseudomonas aeruginosa*.

Royal Jubilee Maternity Service (RJMS)

An outbreak of infection caused by *Pseudomonas aeruginosa* was declared at RJMS Neonatal Unit on 17 January 2012. The earliest sample of *Pseudomonas aeruginosa* which was epidemiologically linked to this outbreak was taken on 15 November 2011. In total, there were five babies infected and 10 colonised babies associated with the strain of pseudomonas linked to this outbreak. Three of the babies died. For one of these babies, pseudomonas was not the reported cause of death.

The strain of pseudomonas linked to the outbreak was detected in water samples taken from five (out of six) taps in the RJMS NICU and from one tap in the RJMS Special Care Baby Unit (SCBU).

Following a programme of actions to control the outbreak there were no further incidents of infection or colonisation with *Pseudomonas aeruginosa* found in RJMS after 25 January 2012 and up to 31 January 2012, the period subject to this review.

Craigavon Area Hospital

One baby was infected and three babies were colonised with a strain of *Pseudomonas* aeruginosa which was linked to Craigavon Neonatal Unit. The baby who was infected with the strain spent several hours in the unit awaiting transfer to RJMS. This baby later died in RJMS NICU.

A number of different strains of pseudomonas were found in swabs taken from taps, sinks and water samples in the Neonatal Unit in Craigavon but no direct link has been established between the strains found in the environmental screening/water testing and the strain which led to infection and colonisation of babies.

Antrim Area Hospital

One baby was found to be colonised with a unique strain of *Pseudomonas aeruginosa* in January 2012, in Antrim Neonatal Unit, following the introduction of screening. This strain has not been linked to any other human or environmental strains associated with these incidents.

Two sinks and water samples from two taps in Antrim neonatal unit were found to be positive for *Pseudomonas aeruginosa* when environmental sampling was carried out.

4.2 Findings in Relation to the First Term of Reference

To investigate the circumstances contributing to the occurrences of pseudomonas infection in neonatal units from 1 November 2011

RQIA's review team concluded that the incidents relating to infection or colonisation with *Pseudomonas aeruginosa*, which occurred in four of the five neonatal units in Northern Ireland, were caused by different strains of the organism. When babies were transferred from one unit to another, there was no spread of that particular strain of pseudomonas to other babies in the second unit. This was a good indication of the quality of infection control.

The outbreaks of infection of *Pseudomonas aeruginosa*, which occurred in the neonatal units at Altnagelvin and Royal Jubilee Maternity Hospitals, were linked to contaminated tap water in the intensive care rooms of the units. There was no definitive evidence to link a cluster of cases in Craigavon Neonatal Unit, and a single case of a colonised baby in Antrim Neonatal Unit to water sources in those units. During phase two of the review further information on taps has emerged and details can be found in section 8.3

The most likely method of spread of *Pseudomonas aeruginosa* from contaminated taps to babies in Altnagelvin and Royal Jubilee neonatal units was through the use of tap water for washing during nappy changes. The use of tap water in RJMS to defrost breast milk may also have contributed to its spread. Invasive procedures are likely to have contributed to the development of infection when babies had been colonised with the organism on their skin.

The review team found that the current design and lack of appropriate accommodation for isolation or cleaning equipment in the Regional Neonatal Intensive Care Unit at RJMS does not facilitate good infection and prevention control practices. The review team recommended that the move to a new unit is expedited as quickly as possible. In the interim, steps should be taken to create improved facilities for segregation of babies with infections and for cleaning equipment and incubators.

Prior to the outbreaks, the trusts' cleaning practices were in line with recommended practice. The previously recommended practice was different from that recommended in interim guidance for neonatal units issued on 28 January 2012 after the outbreaks were declared.

Two trusts advised that before the incidents it was routine practice to use alcohol gels after hand washing in neonatal units. This practice was introduced to all trusts when regional guidance was issued after the outbreaks were declared. The review team recommended that all trusts review their arrangements for independent audits of hand hygiene.

The vulnerability of the babies predisposed them to a very high risk of infection. Following guidance in Northern Ireland, sterile water is now being used for washing during nappy changes in all neonatal units. The review team recommended that this was continued until there was an opportunity for Northern Ireland to fully consider the new guidance issued on 30 March 2012 by the Department of Health (England).

4.3 Findings in Relation to the Second Term of Reference

To review the effectiveness of the trusts' management of the occurrences of pseudomonas infection and colonisation within neonatal units

The review team found that staff in all trusts acted to reduce the risk of spread of infection and to investigate why the incidents had occurred. The review team identified a number of key issues for further consideration, which may have impacted on the speed with which measures to control the outbreaks were put in place.

Information about cases that had occurred in other trusts was not always readily available to inform critical decisions. As in other parts of the UK pseudomonas is not part of existing surveillance systems. A system to routinely collect information on colonisations and infections was established as part of the regional response to the incidents and remains in place. A pseudomonas surveillance system would enable early sharing of information between trusts, and the review team has recommended that a surveillance system is established as soon as possible.

The review team found that it was not a requirement or routine practice across the UK to carry out an investigation of possible causes when a single sporadic case of *Pseudomonas aeruginosa* was detected. It was recommended that *Pseudomonas aeruginosa* is identified as an alert organism for neonatal intensive care and high dependency units. When identified from a sample from a baby, taps and sinks should be tested in rooms that had been occupied by that baby since birth.

Trusts had different approaches to the declaration of outbreaks. The review team considered this may have led to a delay in putting control measures in place when cases of infection occurred. It was recommended that an agreed approach is established across all trusts.

At present, typing of strains of *Pseudomonas aeruginosa* is carried out in England. The review team recommended that arrangements for typing of *Pseudomonas aeruginosa* should be established in Northern Ireland, to reduce the risk of delays in identification of related incidents of infection.

The current neonatal network in Northern Ireland operates on an informal basis. It was recommended that a formal network is established with agreements put in place to ensure that neonatal resources across the region are utilised to best effect and that neonatal units are working to common policies and procedures. The review team recommended that plans should be established to expand the hours of operation of the regional neonatal transfer service for neonates with the goal of establishing this as a 24 hour service. This will require an appropriate training programme to be in place.

4.4 Actions Taken Since the Publication of the Interim Report

The recommendations of the RQIA interim report, published on 4 April 2012, are set out in Appendix A.

On 6 April 2012 the Chief Medical Officer and Deputy Secretary/Chief Estates Officer issued a joint professional advice letter, **HSS(MD)15/2012**, to advise on the publication of the RQIA Interim Report and also on advice published on 30 March 2012 by Department of Health (England) on "Water Sources and potential *Pseudomonas aeruginosa* contamination of taps and water systems - advice for augmented care units".

Circular **HSS(MD)15/2012** is included in Appendix B. Annex A of this circular sets out the agreed programme of implementation for each of the recommendations made in the RQIA interim report.

On 30 April 2012, the Chief Medical Officer, Deputy Secretary/Chief Estates Officer and (Acting) Chief Nursing Officer issued a joint professional advice letter **HSS(MD)16/2012** to disseminate new guidance on "Water Sources and potential *Pseudomonas aeruginosa* contamination of taps and water systems - Advice for augmented care units (including neonatal units caring for babies at levels 1, 2 and 3)". This Northern Ireland guidance was closely based on the guidance, issued in England on 30 March 2012. It incorporated relevant recommendations from RQIA's interim report. The guidance provides advice on:

- Assessing the risk to patients if water systems become contaminated with Pseudomonas aeruginosa or other opportunistic pathogens
- What actions to take if water systems become contaminated with Pseudomonas aeruginosa
- Protocols for sampling, testing and monitoring water for Pseudomonas aeruginosa
- Developing local water safety plans

On 15 May 2012, the Chief Medical Officer, Deputy Secretary/Chief Estates Officer and (Acting) Chief Nursing Officer issued a joint professional advice letter **HSS(MD)17/2012** which sets out guiding principles for the development of decontamination procedures for infant incubators and other specialist equipment for neonatal care. This guidance was prepared to address Recommendation 6 of the RQIA interim report which stated that "Regional guidance on the cleaning of incubators and other specialist equipment for neonatal care should be produced."

On 31 May 2012 DHSSPS has advised that it will issue "Standardised Guidance on Cleaning of Sinks in Clinical Settings". This completes the implementation of recommendation 5 of the RQIA interim report which stated that "The review team recommends that guidance on cleaning sinks should be reviewed so that practice is standardised across all clinical areas".

The HSCB and the PHA advised the review team that work is already underway to take forward the establishment of a formal neonatal network. The review team has also been advised that consultant microbiologists have met to discuss plans to standardise the arrangements for laboratory testing of water. Typing of pseudomonas strains is being taken forward in partnership with the HPA and plans are being developed to improve the accommodation at both RJMS and Antrim neonatal units.

The review team welcomes the programme of actions which has been promptly put in place to take forward the recommendations of the interim report.

5 The Experience of Families

5.1 Introduction

In this section of the report the families tell the story of their baby's illness, how they felt and what impact it had on them and their lives. They speak about what happened to them and also what others did to help them through what was an extremely difficult experience.

The significance of a baby's illness cannot be overestimated, and parents have often struggled alone with feelings that others cannot understand or acknowledge. Parents of premature and ill, new-born babies can experience feelings of hopelessness, fear, shock, sadness and guilt. It is extremely distressing to be the parent of an ill baby and to feel completely powerless to help. The review team decided, therefore, that the families of those babies affected by pseudomonas should be invited to speak directly to them, to learn from their experiences and to ensure that their stories were heard and shared.

Families stated that their decision to share their experiences with the review team was influenced by their understanding that lessons would be learned, and recommendations made to try to prevent such an outbreak happening again. The review team believes that it is also important for those who deal with families of premature and ill babies to hear more about their experiences. Staff must be sensitive to the needs and requirements of parents, particularly when sharing information with them about their baby's care and treatment.

The review team recognises that this was a very difficult time for families to choose to share their experiences. Members of the review team involved in the interviews were impressed by the dignity and honesty of all parents and grandparents that they met. The team thanks the families involved for their participation, openness and willingness to share their experiences.

A letter from Professor Troop was sent, through the trusts, to parents of babies that had been affected by pseudomonas, offering to meet with them. This process ensured that details of any family not wishing to engage with the review team remained confidential. Eight families contributed to the interim report, which reiterated the offer to talk to the review team. Following publication of this report, one further family came forward.

In total, nine families out of twenty five affected by the pseudomonas outbreak contacted RQIA and met with members of the review team. These families included those with babies who had been colonised or infected with pseudomonas and in some cases babies who had tragically died.

Each family met individually with a number of review team members, led by Professor Troop, away from the hospital environment. This helped ease a potentially difficult encounter and should be the blueprint for future similar meetings. Parents were greeted by senior RQIA staff and Professor Troop welcomed them and introduced the members of the review team. Families granted permission for contemporaneous notes to be made of each discussion.

At the end of each interview, families were thanked for their participation and were informed that they would receive a copy of this section of the report, for their approval, prior to publication.

Having received a copy of this section, one family, through their solicitor, has asked not to be associated with this section of the report.

The representatives from Sands and Bliss made all families aware of the possibility of obtaining further support from them, or from other local organisations.

At least one parent was present at each meeting. On several occasions grandparents were also there to share their perspectives, and to provide support. A number of families were also supported by solicitors. The following is an account of the experiences of mothers, fathers and grandparents of babies affected by pseudomonas. While there is no typical story, certain common themes emerged. The experiences of the families are presented under the headings of these themes and a number of quotes from families are included which help to illustrate their feelings.

5.2 Feelings of the Families

Having a baby in a neonatal unit is a stressful situation in its own right and parents described to the review team a "... roller coaster of emotions ...". Families had understandable concerns about their baby being in a neonatal unit. These concerns were then compounded by the knowledge that their baby was colonised or infected by pseudomonas.

Families expressed feelings of fear and isolation when their babies were in the neonatal units. They told the review team how frightening it was to be in the unit with "... lots of flashing lights and monitors ..." Contributing to their fears was the fact that "... there were lots of tubes and wires ..." attached to their very small babies. There were also some families who expressed feelings of anger, as they wondered how their babies had become ill.

Occasionally families felt that they had somehow contributed to their baby's illness by passing on the infection. One set of parents "... wondered if we had contributed by washing our hands in infected water ..." and others noted that "... it would have been difficult to think that something as helpful as handwashing could have caused problems ..."

The review team was told of feelings of powerlessness, as all parents could do was stand by the incubator, particularly as at times they were not allowed to touch their babies.

Some families described how initial feelings of hope, as their premature baby seemed to be progressing well in moving from an incubator to breathing alone, were dashed as they were then informed that their baby had contracted pseudomonas.

However, there were also some positive feelings. Families whose babies were either infected or colonised by pseudomonas and had recovered, or were recovering, told how they were looking forward to a time in the future when their baby could come home.

They also described the positive support that they had received from their wider family circle, and from medical and nursing staff.

5.2.1 Bereaved Families

For parents of babies who had tragically died, the review team was told about the individual circumstances of the birth, short life and death of each of their babies. Their grief and memories were openly shared. Members of the review team were deeply moved by their stories and dignity. Parents described a painful and emotional time watching their baby's condition worsen before they died.

They commented that nursing and medical staff had been deeply upset at the time of their baby's death. The support offered to them by the neonatal units at that difficult time was noted to have been good. One set of parents told how they had taken the opportunity to have their baby christened.

Families described being able to spend time alone with their babies in private following their deaths. They also said that they had been offered the opportunity by the trust of having further support provided for them. The review team noted the strong support all parents had received from their wider family circle.

Some parents said that they did not know about pseudomonas until after their baby's death, which added to their feelings of grief and confusion.

Parents also said that they had been left with several unanswered questions and wanted to know if the death of their baby could have been prevented.

Parents reflected on their feelings regarding their babies. The review team was told "... we have photos of him around the house and we have a great support network at home... we like talking about him. I love to talk about him ..."

5.3 Communication

In most instances, families felt that communication from staff regarding their baby's reason for being in the NICU and the care being taken had been good. In general, families felt that nursing staff were better at passing on information than medical staff, but understood that medical staff had many calls on their time. Nursing staff were described as being "... good, considerate and supportive ..." and had communicated well with families. Nurses were felt to use language that was easier to understand, and in some cases, took more time to explain things.

There were a number of instances however, where it was felt that medical staff had also passed on information very well. One family said that they were "... almost doctors when they left the unit as they knew so much ..." Some families reflected that they had been "... given an opportunity to meet with medical staff right at the beginning ..." and were "... kept informed continually as to how their babies were, and what the next steps in their treatment were going to be ...". It was also noted that doctors had used "... simple language ..." and had explained things in "... layman's terms ..."

However, in a few cases, families felt that medical staff used complex language, "... doctors words ..." which went over their heads to explain their baby's condition.

Simple things like parents being sat down in a chair while the doctor was standing made them feel slightly uneasy as they had to keep looking up at the doctor.

5.3.1 Families of Colonised Babies

Even when pseudomonas caused no symptoms for a baby, families still had to deal with a range of emotions. In the main, the emotion was fear that the colonisation of their baby's skin would develop into a more serious infection.

In neonatal units, in keeping with good infection control practice, colonised babies had been isolated in the same room within the unit. However, this led to some families feeling excluded as a result of the isolation of their baby.

There was a reluctance to speak to other parents on the neonatal unit, due to worry about what these parents might think, and the feeling that somehow pseudomonas might get passed on. In some cases families expressed to the review team that "... we felt alone with pseudomonas ..." and "... we felt that we were the only parents with a baby with pseudomonas ..."

Isolation of babies also caused difficulties for already stretched neonatal units in terms of space available. In one instance this had led to a number of babies being placed in a relatively small area. As a result, parents then felt that they were being treated with less care than they should have been. Families told the review team that "... there were five babies in a room and it was incredibly cramped ..." Another family felt that the room had become "... the dumping ground ..." for those babies colonised with pseudomonas.

Parents of babies who had been colonised also felt that they did not get sufficient information regarding their baby's condition, although they understood that medical and nursing staff were devoting more time to babies that were extremely ill. The perceived lack of information also contributed to feelings of stress and worry about a baby's condition. Parents remained very worried about pseudomonas after discharge from hospital.

5.3.2 Information Passed on to the Families regarding Pseudomonas

The families were asked about when and how they were told about pseudomonas, and about the quality of information they had received. In general, families felt that they had not been made aware in time, that their baby had pseudomonas. In some cases, they were initially not made aware of the seriousness of their baby's condition. Families discussed how pseudomonas had been "... mentioned in a passing conversation ..." and how "... the first time they found out about it was through a leaflet ..."

Families also reflected on how upset they were when they first found out about the seriousness of the situation and "... we didn't suspect that it could end in death ..." and for some "... it was all a bit of a blur..."

There were also issues of confidentiality when parents were trying to get information from neonatal units by phone as the units did not give out information in this fashion. One trust had set up a helpline for parents, but on one occasion a family had difficulty getting the required information via this helpline, as it went through to the unit where the policy was not to give out information by phone.

General meetings, designed to provide information to a group of parents also created some frustration, as passing on detailed information regarding individual babies was impossible due to issues of confidentiality. However, following the meetings parents were given the option of talking on a one-to-one basis with staff, and several took this opportunity.

5.3.3 Media Coverage

The families were asked for their views on the media coverage. It emerged during the meetings that the media had not contacted the families directly and the confidentiality of the families had been well protected. Some, however, felt that the media had been intrusive by their constant presence outside the Royal Jubilee Maternity Hospital. Staff were also upset by the media presence outside the RJMH which they felt was invasive to both parents and staff. Other issues to emerge were that families thought that "... the press attention had intruded into our grief ..." and in one case a family felt "... unable to put our baby's death into the paper because we felt that the media would be looking ..."

Although families in general felt that communication from hospital staff had been good, some families of colonised babies were upset that they were gaining detailed information from media coverage which they felt should have been passed on to them by hospital staff. Staff prioritised communication with bereaved families in order to ensure that they did not hear any information for the first time via the media.

5.4 Impressions of the Neonatal Units

5.4.1 Care of Babies

Families were generally positive about the standard of care that had been provided for their babies, by both medical and nursing staff.

Families reflected how "... staff were considerate, thoughtful and supportive throughout ..." and how medical and nursing staff were "... fantastic ..." One family was also very positive regarding their experience of the transport team which had "... looked after our baby as if he was their own child ..."

5.4.2 Effect of the Outbreak on Staff

The families recognised that dealing with the pseudomonas outbreak was very stressful for staff. Even though they themselves were going through an extremely difficult time, they were very understanding towards staff and what they were also feeling.

They noted that staff had been clearly affected by the situation and that they had been "... shocked and very upset ..." On one occasion the review team was told that a doctor was "... very upset and that he hadn't seen anything like this in twenty years of practising ..." Parents also commented that staff were clearly very stressed and, at times, there appeared to be a slightly difficult atmosphere in the unit which, they felt, was perhaps understandable considering what everyone was going through.

5.4.3 Infection Control in the Neonatal Units

Families were asked to give their experiences and thoughts regarding infection control in neonatal units and what advice or instruction they had been given by staff. There were isolated examples of not remembering being told about infection control, but most families felt they had been well informed and that staff infection control standards were good. The review team was told that "... from the very first visit we were instructed about how to wash hands ..." and "... we were instructed to remove watches and roll up sleeves ..." Families noted that they had been given instructions to wash hands in warm water and soap and then use foam every time they left the unit. They also noted that staff were always washing their hands and using alcohol gel constantly.

5.5 What Could Have Been Done Better

The families were asked what, in their opinion, could have been done better. In a number of cases families felt that nothing could have been done better. In other cases it was felt that communication could have been improved. In certain instances the families felt that they had not been informed about pseudomonas early enough and that they also were not informed of the seriousness of their baby's illness. The families with babies that had been colonised felt that they could have been treated with more care and attention.

One family in the early stages of bereavement felt that they could perhaps have held their baby more and sooner. Due to the use of sterile water, it was also noted there were no baths available and staff were unable to demonstrate how to bath a baby prior to discharge. One set of parents felt that they were being judged as too young to cope.

5.6 Conclusion

It is essential in situations with such a tragic outcome that learning takes place. It is important that clinical care of a high standard is delivered in all circumstances. However, the needs and feelings of families affected by the illness of a relative must also be taken into account. This is particularly important when dealing with babies.

In general, families were satisfied with the standard of care provided for their babies but felt that communication, in particular the level of language and information regarding the seriousness of the pseudomonas colonisation/infection, could in some cases have been improved.

During such an outbreak, clinical staff, both medical and nursing staff, are under great pressure, and this was recognised by the families. It is acknowledged that clinicians, due to the bond that they have established with families are best placed to communicate information to parents and wider family groups. However, medical staff should use plain language when giving information. Where possible, information should be passed on in an appropriate, private setting. Parents should also be given the opportunity to have support, either from other family members or through external support organisations.

In some instances clinicians were concentrating their efforts on babies who were very sick, but as a consequence of this, parents of babies who had been colonised felt that their concerns were not being addressed.

Specific leaflets giving information for parents whose babies had been colonised and a separate leaflet for those with babies who had been infected with pseudomonas, would have helped. However, leaflets should not replace personal contact.

Parents need consistent information in a timely manner. Parents must be informed before information appears in the media. Medical and nursing staff should have daily meetings to agree the content of such information. This should also be communicated to staff at the beginning of each shift. In small units it is easier to have one-to-one contact with parents however in larger units this becomes more difficult.

General meetings involving a number of parents allow information to be passed on to larger numbers. However, the parents told the review team that doctors did not feel they could explain what was going on in the unit due to confidentiality. The parents felt this was unsatisfactory.

Clinical staff should be provided with sufficient support to allow them to concentrate on clinical matters, with other roles taken on by non-clinical staff. This could all be set out in a communications plan, developed with the assistance of a trust communications department.

Professor Troop and the members of the review team thank sincerely all family members who came forward and shared their experiences.

6. Governance Arrangements

To review the effectiveness of the governance arrangements across all five health and social care trusts with regard to the arrangements for the prevention and control of infection and all other relevant issues in their respective neonatal units

6.1 Introduction

On consideration of the findings set out in the interim report, the review team determined that the following areas of organisational governance should be reviewed in preparation of this final report:

- Governance arrangements for ensuring that appropriate action is taken in response to circulars and advices
- Governance arrangements in relation to the management of water distribution systems in hospitals
- Governance arrangements in relation to the prevention and control of infection
- Governance arrangements in relation to the reporting and follow-up of incidents

From the evidence submitted, and through discussion with board members and senior managers, all trusts have established systems in place for integrated governance across their respective organisations.

The review team has also carried out an assessment of how organisations responded to relevant circulars and advices issued from September 2010 to January 2012 in respect of water sources and potential infection risk to patients. The review team has been provided with an extensive set of evidence in this regard.

6.2 Governance Arrangements for Ensuring that Appropriate Action is taken in Response to Circulars and Advices

The review team discussed trust arrangements to ensure that when circulars and guidance are received by the trust, there are appropriate arrangements in place to ensure that relevant action takes place.

Trusts advised that the number of circulars and advices received from a variety of sources is significant. One trust had recorded more than 50 such documents in the previous quarter. Trusts have established systems for the central recording of receipt of relevant documents and for allocating responsibility for follow up action. Systems for managing circulars have been strengthened in response to the volume received and in particular to the recognition of the risks, if appropriate action does not take place. Some trusts had reviewed their procedures in the light of the learning from the pseudomonas incidents.

Trusts emphasised the importance of ensuring that all relevant sources of advice are received through a single point of entry which is the Office of the Chief Executive, even if copies are distributed to other trust officers as well. Each trust has a system for follow up of actions for circulars received. These systems differ between trusts. Some trusts take forward action by allocating responsibility to a relevant director. The South Eastern Trust has established a triage arrangement so that all circulars are reviewed by a team who meet fortnightly to carry out this function and review compliance. The Southern Trust also has a triage process in place. The Western Trust advised that their Quality and Standards Sub-group formally reviews, monitors and reports on compliance with circulars to the Western Trust Governance Committee.

6.3 Governance Arrangements in Relation to the Management of Water Distribution Systems

6.3.1 Standards and Guidance on Water Management

There are two major precedent documents for the safe management of water systems in healthcare facilities. HSC organisations are required to have in place protocols that provide best practice engineering standards and policy to enable management of this duty of care.

The Health and Safety Executive sets out an Approved Code of Practice and guidance in document L8 called "The control of legionella bacteria in water systems" (Third Edition 2000). The Approved Code of Practice L8 includes requirements for organisations in relation to:

- identification and assessment of risk
- risk management responsibilities, training and competence
- preventing or controlling the risk from exposure to legionella bacteria
- record keeping
- responsibilities of manufacturers, importers, suppliers and installers

L8 also provides guidance on a wide range of issues related to water management, for example, monitoring, cleaning and disinfection, management of hot and cold water systems, and treatment and control systems. L8 requires organisations to have a written scheme in place in respect of controlling risk from *Legionella*. The organisation should appoint a person to take day-to-day responsibility for the control of the hot and cold water services and to be responsible for assessing and controlling any identified risks from *Legionella*.

A Department of Health (DoH), Health Technical Memorandum (HTM 04-01 Part B Operational Management) provides guidance to HSC Trusts in Northern Ireland entitled "The control of *Legionella*, hygiene, "safe" hot water, cold water and drinking water systems" (October 2006). This document provides guidance on areas such as staff training and temperature management to control *legionella*. It recommends that for healthcare facilities flushing of taps should be applied on a daily basis as part of the cleaning process. Regular flushing should be in place for sporadically used outlets.

6.3.2 Arrangements in Place in HSC Trusts

The review team was provided by trusts with documentary evidence as to the arrangements in place and actions taken in relation to the management of water systems. Meetings were held with estates staff during Phase One and governance arrangements for water management were discussed with trust directors during Phase Two.

The arrangements for appointing a "Duty Holder" in relation to L8 varied between trusts. In three trusts this was the chief executive and in two a director had been appointed to this role which is to lead corporate strategy and oversight of water systems management arrangements.

Trusts have identified a "Responsible Person" in line with their duties under L8. The arrangements did differ between trusts. In Belfast the Water Safety Group" has been identified as the "Responsible Person". This arrangement was discussed by the trust with the Health and Safety Executive for Northern Ireland. Not all trusts had a named deputy for this role.

All trusts have water groups which are linked to trust governance structures. Groups have been established for different time periods and there are differences in the constitution and terms of reference for the groups. In some trusts, the groups evolved from earlier *Legionella* working groups. Belfast Trust decided to establish a specific water safety group in 2009 to facilitate the management of risk associated with *Legionella*. It is chaired by a medical microbiologist.

The review team was provided with copies of trust documentation in relation to water management. There were differences in the documentation provided. Four trusts provided copies of written schemes for the prevention and control of *Legionella* which is a requirement under L8. Belfast Trust shared a draft water management plan which has been consulted on with HSENI.

All trusts provided evidence that a training needs analysis had been carried out to identify requirements of staff undertaking water management, maintenance and operation. Evidence submitted by trusts did not always provide assurance that individuals with specific responsibilities in relation to water management were receiving accredited training in relation to their roles.

Three trusts had identified management of water quality on their corporate risk register.

Trusts provided some documentation as to governance arrangements for provision of assurance on their processes. This included self-assessment tools in relation to controls assurance.

Trusts have carried out risk assessments in relation to water systems as required under L8. The review team found that the approach used and stage of completion was different between trusts. Plans to carry out actions to improve compliance of systems were in place but the review team was advised that additional resource would be required if full compliance was to be achieved.

The review team concluded that the evidence submitted by trusts in relation to governance of water management displayed that all trusts knew and accepted the need for good water management.

Having considered the evidence submitted, the review team recommends the following actions to strengthen arrangements for the governance of water management:

- Trusts should establish arrangements for independent validation of their selfassessment processes for water management compliance with statutory requirements and guidance
- Trusts should maintain an evidence file of compliance with L8 and HTM 04-01
- Trusts should maintain up to date registers of all those with named responsibilities under Approved Code of Practice L8 and that each is provided with written authorisation to carry out their statutory functions in water management
- Trusts should ensure that their written schemes are kept up to date to reflect changes in procedures and facilities
- Trust should also review the training needs of staff with prescribed functions in water management and ensure appropriate accredited training is provided when required
- Trusts should develop Water Safety Plans for Legionella, Pseudomonads and other opportunistic water pathogens as recommended in Annex A (2) of the DHSSPS Circular HSS (MD) 16/2012 issued on 30 April 2012
- Trusts should develop an annual action plan for water management which should be submitted to Trust Board for approval

6.3.3 Arrangements for Flushing of Taps

All trusts now have arrangements in place to comply with guidance on flushing of taps in neonatal units which was issued following the outbreaks.

The Department of Health Guidance for HSC Trusts (HTM 04-01 Part B) recommends that regular flushing arrangements should be in place for sporadically used outlets. The review team asked trusts for information as to how trust flushing arrangements applied to taps in their neonatal units between October 2011 and January 2012. Trusts provided the following information.

Belfast Trust

In Belfast, the trust confirmed that neither manual nor automatic flushing arrangements were in place for the period 1 October 2011 to 31 January 2012 for taps in the neonatal unit. These outlets were not deemed as being infrequently used and, as such, no arrangements were in place.

Northern Trust

There are no records of planned flushing of taps in the neonatal unit during the period 1 October 2011 to 31 January 2012 as there were no "little-used outlets" as defined in L8 and HTM 04-01, during this period. The taps in Antrim Hospital's Neonatal Unit were lever-action manual taps with no automatic flushing mechanism.

Southern Trust

Up to 30 January 2012, the taps in Daisy Hill and Craigavon neonatal units were not deemed to be infrequently used and therefore, under the guidance at that time, flushing of these outlets was not required.

Out of the 11 taps in the Craigavon Neonatal Unit, five were sensor taps and these had been fitted with auto drains and they were set to flush for 1 minute in every 24 hours. In the SCBU in Daisy Hill Hospital, 10 taps out of the 20 in the unit were sensor taps and were again set to flush 1 minute out of 24 hours.

South Eastern Trust

The trust policy (June 2010) is that water outlets (showers, baths, wash-hand basins, sinks etc) at clinical level which are infrequently/not used should be identified to the estates department and placed on a programme of regular flushing or removed. Flushing involves a minimum of twice weekly flushing for 2 minutes once the water has run hot/cold as appropriate. The flushing of low use outlets at clinical level must be logged and signed. These records must be available for internal/external inspection.

Western Trust

Estates services in the trust had a programme of weekly flushing of taps in the neonatal unit. This was in place at 1 October 2011 and continued after 12 December when additional daily flushes were initiated. This weekly flushing by estates staff ceased at the end of January after the taps were changed.

From 12 December 2011 an additional daily flushing schedule was introduced. This schedule consisted of twice daily flushes – during the day shift by support services staff and during the night shift by the nursing staff on the neonatal unit.

The Western trust provided copies of the weekly records of the implementation of the flushing regime for the taps in Altnagelvin Hospital for this period.

6.4 Response to Relevant Circulars and Advices issued from September 2010 to January 2012 in Respect of Water Sources and Potential Infection Risk to Patients

The review team has been advised of five circulars and advices which were issued between September 2010 and January 2012 to trusts in respect of water sources and potential infection risks to patients:

- 15 September 2010, Circular HSS (MD) 34/2010: "Water Sources and Potential Cross Infection Risks from Taps and Basins – Interim Advice"
- 1 July 2011, a Professional Estates Letter **PEL(11)13:** "Water Systems and Potential Infection Risks"
- 23 August 2011, an alert notice, NIA-2011-002 "Flexible Water Supply Hoses"
- 22 December 2011, Circular HSS (MD) 31/2011: "Water Sources and Potential Infection Risks to Patients"
- 28 January 2012 Circular HSS (MD) 4/2012: "Interim guidance on Pseudomonas and Neonatal Units"

The review team has requested and received details of actions taken by HSC trusts in respect of each of these circulars and advices.

6.4.1 HSS (MD) 34/2010: Water Sources and Potential Cross Infection Risks from Taps and Basins – Interim Advice

HSS (MD) 34/2010 was issued in Northern Ireland on 15 September 2010 following circulars issued in Wales and England in August 2010. The circular advised that DHSSPS had become aware of outbreaks of infection caused by pseudomonads in England and Wales. The Northern Ireland circular was worded very similarly to the circular which had been issued previously in England. The incidents had occurred in augmented care wards (such as adult or neonatal intensive care, renal and burns units). Hand hygiene stations had been identified as the source. There had been evidence of persistent colonisation of the faucets (taps).

The circular required trusts to assess the risk to their patient population and, where appropriate, establish if the water used in hand washing had an unacceptable bacterial count. The circular provided advice on the use and cleaning of hand hygiene stations and actions to be taken if contamination of faucets was found. Trusts were asked to review their engineering protocols and to ensure that manufacturer's instructions in regard to installation and maintenance had been followed.

All trusts provided evidence that the circular was distributed to relevant staff within their organisations in line with the local arrangements for distribution.

On 16 September 2010 the PHA provided each HSC trust with information about the number of Pseudomonas bloodstream infections which had been reported for 2005-2010 for each hospital in the trust. The aim was to share this information to assist with actions being taken forward by the trusts in relation to the circular.

Figure 6.1 shows the information which was provided at the time about the number of cases of pseudomonas blood stream infections (both children and adults) in Northern Ireland during the period from 2005 to 18 August 2010.

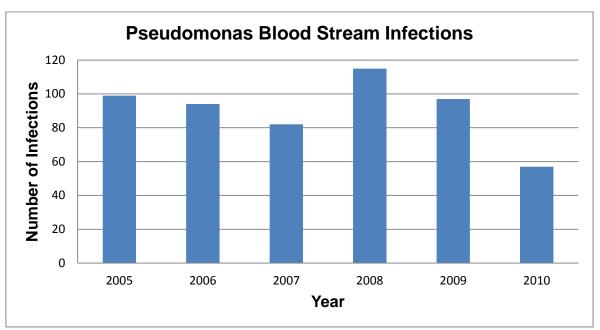


Figure 6.1 Number of reported blood stream infections from pseudomonas In Northern Ireland from 2005 to 2010 (up to 18 August 2010)

Table 6.2 gives the number of cases of pseudomonas blood stream infections (both children and adults) in hospitals during the period from 2005 to 18 August 2010. It is important to emphasise that the figures show numbers of infections and cannot therefore be directly compared across hospitals as the numbers of treated patient vary significantly.

Hospital	2007	2008	2009	2010
				(up to18 August)
Altnagelvin	6	7	9	8
Antrim	6	7	15	5
Belfast City	15	26	13	10
Belvoir Park	5	8	1	0
Causeway	0	9	3	2
Craigavon	11	4	6	7_
Daisy Hill	4	2	0	3
Downe	1	3	0	3
Erne	3	3	4	0
Lagan Valley	1	1	1	1_
Mater	0	9	10	2
Mid-Ulster	2	2	0	0
Musgrave	0	0	1	1
RBHSC	1	6	6	1
Royal	15	18	16	8
Royal Maternity	1	0	1	1
Tyrone County	1	2	0	0
Ulster	9	8	9	5
Whiteabbey	0	0	0	0
Unknown	1	0	0	0
Total	82	115	97	57

Table 6.2: Number of reported blood stream infections from pseudomonas by hospital from 2007 to 2010 (up to 18 August 2010)

ACTIONS TAKEN

Belfast Trust

On 5 September 2010 the Belfast Trust Water Safety Group considered the circulars issued in England and Wales prior to the release of the Northern Ireland circular. A decision was taken that as there was no clarity as to how or when water should be tested, the trust would follow the Welsh guidance that water sampling should only be undertaken from taps on a unit affected by an outbreak of an infection such as pseudomonas. At the time the trust did not have an outbreak and no recommendations for testing were made. On 24 November 2010 a memo was issued following a meeting of the trust Infection Prevention and Environmental Cleanliness Committee which:

- 1. emphasised the importance of using hand washing basins only for the purpose of hand washing
- 2. identified hand washing facilities as the source of infection caused by environmental pseudomonas like organisms in England and Wales

- 3. recommended the application of approved alcohol gel to hands following hand washing and before an invasive procedure in augmented care areas
- 4. directed that Patient Client and Support services should ensure that taps were cleaned before the basin to reduce the risk of contamination of the taps

During October/November 2010 an audit of clinical compliance of wash hand basins was undertaken in augmented care areas. The audit did not include the neonatal unit as there were plans for it to be refurbished.

As there was no evidence that the trust had a problem with pseudomonas infection in augmented care areas, the installation of point of use filters was not considered. Following discussion at the Water Safety Group, the trust concluded that its estates engineering systems were compliant with the appropriate sections of ACOP L8 and HTM 04-01.

Northern Trust

Following receipt of the circular a trust consultant microbiologist worked with estates services to risk assess the water supply for the trust and assess the risk to the patient population.

The clinical notes of all patients in Antrim Hospital who had a blood culture positive for *Pseudomonas aeruginosa* in the period 1 January 2009 to 31 October 2010 were reviewed by two medical microbiologists. There was no evidence of clustering in any clinical area; this included the augmented care areas. Review of all positive bacterial culture results for infants in the Neonatal Unit revealed only one patient with a positive *Pseudomonas aeruginosa* culture from a nasal swab over a time period of January 2009 to January 2012. Clinical surveillance did not indicate that there was a specific problem in NICU with respect to *Pseudomonas aeruginosa*.

An audit was carried out to ensure that the purpose of each sink was evident through clear signage ie: hand washing only or equipment decontamination only and was being used appropriately. Decontamination of sinks was managed through domestic services as per guidance on 6 February 2012 to ensure proper cleaning was taking place.

Installation of point of use filters was not considered by the trust to be of any benefit and would be high maintenance.

South Eastern Trust

The circular was triaged by the clinical guidelines group and forwarded to the Water Safety Group for action. The group concluded that as there was no evidence of a clinical problem at that time there was no requirement to assess the bacterial levels in the water.

The Water Safety Group confirmed that site engineering protocols were in accordance with current guidance and HTM 04-01. A comprehensive external legionella risk assessment had been carried out in July 2009 at the Ulster Hospital facility.

The Water Safety Group also actioned the following:

- 1 sinks were checked for damage and cleanliness
- 2 supply of hand towels and soap checked
- 3 regular monitoring of hand hygiene
- 4 use of dedicated hand washing sinks for hand washing alone
- 5 observation of practice

Regular monitoring of hand hygiene practice was already in place within the trust.

Southern Trust

The circular was considered by the infection prevention and control team, estates and facilities department and discussed at a senior management governance team meeting on 29 September 2010.

A letter of response to the circular was issued on 27 October 2010 from the trust medical director in consultation with estates, facilities, microbiology and infection prevention and control teams following discussion and review at the trust senior management governance team meeting on 20 October 2010.

The clinical director (infection prevention and control) carried out an assessment of cases and there was no evidence of increased incidence of pseudomonas. As there was no clarity as to how or when water should be tested, a Southern Trust microbiologist discussed the need for water/tap sampling with colleagues from the Belfast Trust. It was agreed that water would only be tested if more than one clinical case (linked in time and place) was identified. As there was no evidence of linked cases at that time, routine testing was not undertaken.

The trust confirmed that current site engineering protocols were in accordance with current guidance and HTM04-01 and manufacturer's instructions re installation and maintenance.

The trust confirmed that hand washing stations were used only for hand washing and that routine IPC hand hygiene training reinforced this message as well as teaching staff to avoid contamination of the faucet. This was subject to ongoing monitoring by the IPC team. Signage was developed that was placed in all hand washing stations with temporary signs in place at the time in the neonatal unit and the SCBU.

The Southern Trust assessed the CMO guidance against current practice in relation to hand hygiene which was based on the World Health Organisation (WHO) hand hygiene guideline.

The Southern Trust implemented the WHO hand hygiene guideline in December 2008, which recommends:

- use of alcohol hand rub on physically clean hands as it is superior to hand washing
- hand washing with soap and water is recommended for physically dirty hands or visibly soiled hands

WHO hand hygiene guidance does not recommend the use of alcohol hand rubs after hand washing to prevent dermatitis among healthcare workers. Based on the assessment of clinical cases it was not felt necessary to deviate from this practice at this time.

There was no clinical evidence that the trust has an issue with pseudomonas bacteraemia in augmented care areas. As there was good hand hygiene practice in place, the fitting of these filters was not required. Therefore the trust did not fit point of use filters.

Western Trust

Following receipt of the circular, the trust established an integrated multidisciplinary water safety group. A plan was agreed to assess any potential risk areas and agree a water sampling programme. A review of blood cultures was undertaken to ascertain evidence of any connection between taps and infection and no connection was established.

The Water Safety Group established a policy and a written scheme for legionella and compliance with guidance and HTM 04-01 was established.

Ward managers were advised not to use clinical hand washing sinks for disposal of body fluids and a notice was issued through the Director of Nursing's office to lead nurses and ward managers with regard to this.

The trust did not advise staff on the use of alcohol gel following hand washing at that time because surveillance of blood stream infections showed no evidence of association between water contamination and clinical cases. The trust decided against the installation of point of use filters for the same reason.

6.4.2 PEL(11)13: Water Systems and Potential Infection Risks

PEL(11)13 was issued on 1 July 2011. The letter provided a summary of the key outcomes of a workshop held in May 2010 to share lessons from the Belfast Trust from a case study of control of legionella in a healthcare facility. PEL(11)13 set out a number of actions to reinforce good practice for the management of water delivery systems in health care facilities to minimise and manage the risk of contamination by organisms such as legionella and pseudomonas.

Actions required included a review of written schemes for the control of exposure from legionella bacteria in water. Reviews were to be carried out using a team approach involving infection control teams and estates management teams to identify potential risk areas. Water sample testing was to be undertaken, if not already in place, for areas where patients may be more vulnerable to the risk of infection from legionella.

Water systems were to be reviewed to identify and remove water outlets that were not in use and deadlegs within the hot and cold water systems as part of ongoing system maintenance. Chief executives were to provide a statement of assurance to DHSSPS, by 31 August 2011, that written schemes had been reviewed.

ACTIONS TAKEN

Belfast Trust

The trust had already formally instigated a Water Safety Group on 29 January 2010 and agreed the chairmanship, membership, terms of reference and reporting mechanisms. The group was multidisciplinary and its purpose was to ensure that as far as is reasonably practicable that potable (drinking) and non-potable (non-drinking) water is of the highest quality at the point of use to assist with safe and effective provision of services for all patients, staff and the general public.

The trust had already developed a sample testing regime in prioritised areas which was demonstrated during the workshop referenced in PEL (11)13.

The trust has undertaken extensive work in the identification and removal of deadlegs in prioritised areas across the trust as part of an on-going system of maintenance. This work was on-going at the time of issue of the PEL.

The trust advised that a response was sent to DHSSPS on 2 February 2012 – this had been prepared at the time but had not been forwarded to DHSSPS by the due date of 31 August 2011 due to an oversight.

Northern Trust

PEL (11)13 was discussed at a meeting of the water group on 18 August 2011.

The water safety group was formalised and a responsible person and deputy responsible person for water were appointed and written schemes for controlling the risk from exposure to legionella were reviewed.

A water sampling scheme was already in place in the trust adhering to guidance contained in L8 and HTM 04-01.

The trust confirmed that risk assessments were on file for all trust owned facilities and that the programme to carry out a formal review of the legionella risk assessment for each facility including line diagrams was well advanced and would be completed within the financial year.

Risk assessments have been carried out on all trust facilities. Deficiencies identified in the risk assessments were prioritised for remedial work which has been ongoing since 2007.

A response was sent to DHSSPS on 25 August 2011.

South Eastern Trust

A water safety group was formed on 28 July 2010 and a responsible person and deputy responsible person for water were appointed. Terms of reference and group membership were agreed.

Previously risk assessments and development of written schemes were either undertaken in house or by appointment of external contractors. The trust in conjunction with the procurement and logistics service, prepared a tender for the provision of risk assessments and written schemes.

A programme of extensive and ongoing sampling has been undertaken throughout the trust estate. Sampling carried out by a specialist contractor appointed by the trust is also undertaken at prioritised high risk sites throughout the trust.

The trust Water Safety Group considered PEL (11) 13 and reported that a removal programme for underused outlets was in place and flexible hoses in high risk areas were being replaced.

A response was sent to DHSSPS on 12 September 2011.

Southern Trust

The trust had already formally established a trust wide Legionella Control Group with representation from the IPC team, Medical Director and estates Management. Following this the trust completed its regular bi-annual Legionella risk assessment in all facilities. An action plan to address high level risks was developed. In-house works commenced at that time.

The trust arrangements for the management of water systems and potential infection risks were set out in its document – The Control of Legionella.

A full review of the existing legionella controls commenced in January 2011.

Trust operational procedures – "The Control of Legionella, Hygiene, Safe Hot Water, Cold Water and drinking water systems" were developed and agreed in September 2011.

Estate services representatives and infection control staff then identified high risk areas across the estate and testing for legionella has been established for these areas. Water testing commenced in September 2011 and continues.

Since 2003 a specialist contractor has been appointed by the trust to carry out bi-annual risk assessments for water systems. As a result of these risk assessments the trust has undertaken extensive work to minimise the risk of legionella and this work has included removal of dead legs and not in use water outlets.

A response was sent to DHSSPS on 30 August 2011.

Western Trust

A water safety group was formed in December 2010 with both estates and infection control representation.

Current written schemes were reviewed and a trust wide written scheme for the prevention of legionella has been developed.

The written scheme details procedures and actions covering testing of water systems as per L8 and HTM 04-01. The trust has in place a water quality testing programme in line with risk assessments and remedial actions are taken in line with the protocol set out in the written scheme.

Trust properties are being systematically reviewed on a prioritised basis to identify areas of non compliance such as deadlegs, underused installations and use of inappropriate materials. There is also an on-going programme in place of flushing systems in buildings or parts thereof which are not currently in use. Buildings not in use for extended periods are drained where possible and the entire system disinfected before being returned to use.

A response was sent to DHSSPS on 30 August 2011.

6.4.3 NIA-2011-002: Flexible Water Supply Hoses

On 23 August 2011, an alert notice, NIA-2011-002, was issued by the Northern Ireland Adverse Incident Centre (NIAIC) relating to flexible water supply hoses. This followed alerts issued in England and Wales. The alert drew attention to the risk that some flexible hoses in potable water supply systems may have an enhanced risk of harbouring legionella and other organisms. Organisations were asked to identify flexible hoses and carry out a risk assessment for possible contamination with harmful microorganisms. Action was to be completed by 1 January 2012.

ACTIONS TAKEN

Belfast Trust

A response was sent to DHSSPS to confirm that action was completed by 13 January 2012. The Belfast Trust advised the review team that current policy is not to fit flexible hoses as per PEL (11)13. The Belfast Trust is now working with HPA on a suitable alternative without the current associated risks.

Northern Trust

A response was sent to DHSSPS to confirm that action was completed by 7 March 2012. The trust advised that flexible water supply hoses are not in use within the neonatal unit in Antrim Hospital.

South Eastern Trust

A response was sent to DHSSPS to confirm that action was completed by 2 February 2012. The trust advised that the South Eastern Trust policy is that the trust does not specify the use of flexible hoses for all new installations or refurbishments.

Southern Trust

A response was sent to DHSSPS to confirm that action was completed by 3 April 2012. As a result of guidance from Legionella experts the trust decided to cease the use of flexible hoses since 2010.

Western Trust

A response was sent to DHSSPS to confirm that action was completed by 6 February 2012. The Western Trust policy is that installation and use of flexible hoses is prohibited. The Trust Estates Department has been systematically working through the removal of flexible hoses where these exist within trust facilities using a risk based approach.

6.4.4 HSS (MD) 31/2011: Water Sources and Potential Infection Risks to Patients

On 22 December 2011, Circular HSS(MD)31/2011 was issued for action by HSC organisations. The purpose was to remind organisations of the potential risks posed by water in healthcare facilities and to reinforce the messages contained in HSS (MD) 34/2010 and PEL(11)13. Organisations were advised that similar events had now been reported in Northern Ireland to those which had led to the issue of HSS (MD) 34/2010. The circular set out actions to be followed where there was contamination of faucets in an augmented care ward to protect patients. The circular advised that research, commissioned by the Department of Health in England into the potential risks associated with pseudomonas contamination in wash hand basin water taps, had been largely completed.

Actions required included ensuring that the contents of both HSS (MD) 34/2010 and PEL(11)13 were brought to the attention of all relevant staff. Organisations should ensure that they were fully compliant with the good practice outlined in relation to both the management of water systems and infection control practice.

Systems and processes should be in place to provide robust assurance, and documentary evidence, of compliance with best practice for the management of water systems and infection control practice (particularly in relation to hand hygiene and/or aseptic non-touch technique).

ACTIONS TAKEN

Belfast Trust

The circular was disseminated on receipt to the appropriate staff across the trust and a decision was taken that it would be discussed at the next meeting of the water safety group on 24 January 2012. This decision was based on the fact that a Water Safety Group had been in existence since January 2010 and had already considered relevant guidance which had included DH guidance (letter ref 14720), HSS 34/2010 and PEL (11) 13.

Northern Trust

Following receipt of guidance, the circular was disseminated to relevant staff and was to be formally considered at next meeting of the Infection Prevention and Control group.

The trust explained that ongoing control of legionella programmes were already in place as well as the rectification of deficiencies identified in reviews of risk assessments for all sites which had been completed in December 2011.

South Eastern Trust

The circular was forwarded to the Water Safety Group. In the week commencing 3 January, members of the IPC team reviewed high risk areas in the trust (ICU, NNU/Maternity, theatre) for non compliant sinks to inform the Water Safety Group. No issues were identified in clinical areas. Some issues were identified in secondary areas. In ICU these were being taken forward by the Water Safety Group. Sinks in NNU were found to be compliant.

Southern Trust

The circular was distributed by the Chief Executive on 22 December to the Medical Director and Lead Directors in Estates, Infection Prevention and Control and Acute Services for action. It was subsequently cascaded by the Clinical Director for IPC to the IPC Team and Microbiologist on the 23 December. It was circulated to all Clinical Staff on 28 December 2011 by the Medical Director and was distributed to, and considered by, the Trust HCAI Strategic Forum [20 January 2011]. The membership of the HCAI Strategic Forum includes representation from PHA. The Forum considered the Trust to be compliant.

Western Trust

Following receipt of the guidance, an email was sent from the chief executive to the medical director, director of nursing, head of infection prevention and control and copied to the assistant director, facilities management. The head of infection prevention and control confirmed that the trust had already implemented most of what is contained in the guidance. There were a few areas of wider learning which the director of women and children's services would take to the corporate management team.

6.4.5 HSS (MD) 4/2012: Interim guidance on Pseudomonas and Neonatal Units

On 28 January 2012, a circular, HSS (MD) 4/2012, was issued to HSC trusts, the PHA and the HSCB providing interim guidance on pseudomonas and neonatal units. This guidance had been developed in consultation with the HPA in England.

HSS (MD) 4/2012 stated that, as a precautionary measure for immediate action, all water from hand washing stations should be assumed to be potentially contaminated until proven otherwise. For this reason there should be no direct or indirect contact between this tap water and the babies themselves. Sterile water should be used for all contact with babies including cleaning incubators or other equipment."

HSS (MD) 4/2012 set out advice on water testing and taps, correct use of hand hygiene stations and cleaning of taps and sinks.

It advised that the PHA was undertaking environmental risk assessments of each unit to determine what specific action needed to be taken. The circular included a Northern Ireland interim protocol for testing of water from clinical hand wash stations for *Pseudomonas aeruginosa* to be put in place until further notice.

ACTIONS TAKEN

The review team found that the circular was disseminated rapidly to relevant staff in each organisation and that the required actions were put into effect in each trust including the use of sterile water for all contact with babies, where this was not already in place, and water testing regimes for clinical wash hand basins.

6.4.6 Conclusions of the Review Team in relation to response to circulars

The review team has found that all trusts considered the relevant circulars and advices when they were received by the organisations. The circulars were processed through the trust mechanisms for recording and dissemination. In general, actions were taken to consider and implement the guidance.

The review team found that the actions taken differed across trusts to some extent. Following the first circular, there was a difference in how trusts responded with regard to the advice on using alcohol gel following hand washing.

From the information provided there was evidence that the wording of the initial circular issued on 15 September 2010 was interpreted as indicating that, if a risk assessment did not indicate that there was a local problem with infection, additional water testing was not required to be put in place.

Trusts advised that the Circular issued on 22 December 2011 was regarded as a reminder for action on earlier communications following local incidents and did not identify immediate new action to be put in place. Trusts considered that they had already taken forward the actions issued on the earlier circulars. Three trusts advised the review team that they were not aware of which incidents were being referred to in the circular. This circular was distributed to relevant staff on receipt with plans to discuss it at the next meeting of the relevant trust groups.

The review team has concluded that the circulars and advices were taken forward in keeping with the governance arrangements in place in each trust.

6.5 Governance Arrangements in Relation to the Prevention and Control of Infection

6.5.1 Prioritisation of Prevention and Control of Infection

The review team found that the prevention and control of infection in hospitals is a high priority for all HSC organisations. Challenging targets have been set by the DHSSPS on an annual basis to drive down the numbers of cases of *Clostridium difficile* and MRSA. These are subject to regular performance monitoring by the HSCB, working in collaboration with the PHA. Regional standards have been determined for healthcare hygiene and cleanliness, which are subject to unannounced and announced monitoring carried out by RQIA.

Specific interventions using care bundle approaches have been put in place to tackle issues such as ventilator acquired pneumonia, infection linked to insertion of intravenous lines and surgical site infection which includes orthopaedics and caesarean section.

Non-executive members of trust boards advised the review team that infection prevention was a clear priority at board level and their role in this action had been highlighted through an initiative led by the DHSSPS. They advised that performance against the regional targets was closely monitored by trust boards.

Trusts have established local structures to oversee governance in relation to infection prevention and control to link into their specific arrangements for ensuring that there is integrated governance across the organisation. In each trust, there is a committee responsible for oversight of infection prevention and control. This reports through the trust governance structures to the trust board. In some trusts, non-executive board members are part of the infection prevention and control committee.

6.5.2 Evidence of Performance

The review team considered information provided by trusts and regional information on trends in *Clostridium difficile* and MRSA as benchmarks of performance on infection prevention and control.

Table 6.3 and Figure 6.4 show trends in the numbers of cases of *C. difficile* among inpatients aged 65 years and over during the past five years. The total number of cases fell from 1,019 in 2007-08 to 327 in 2011-12, which is a significant achievement.

The information provided in the following tables (6.3 and 6.5) and figures (6.4 and 6.6) is not directly comparable between trusts as the numbers and case mix of patients treated differs across organisations.

	2007/08	2008/09	2009/10	2010/11	2011/12
Belfast Trust	280	327	163	147	117
Northern Trust	297	172	102	103	75
South Eastern Trust	199	135	98	80	72
Southern Trust	134	164	37	17	28
Western Trust	109	104	71	46	35
Total	1,019	902	471	393	327

Table 6.3: *C. difficile* episodes among inpatients in Northern Ireland aged 65 years and over by financial year and HSC trust. Source: Public Health Agency: *C. difficile* Surveillance Quarterly report (Q1 2012)

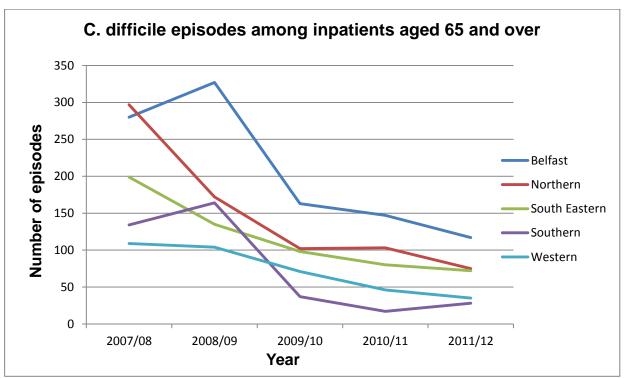


Figure 6.4: Trends in *C. difficile* episodes by Trust in patients aged 65 and over. Note: These are number of cases and do not take into account bed numbers by Trust.

Table 6.5 and Figure 6.6 show trends in the number of cases of MRSA bacteraemias patient episodes for each trust for the past five years. This indicates that there has been a downward trend with the overall numbers falling from 221 to 96 during this period.

	2007/08	2008/09	2009/10	2010/11	2011/12
Belfast Trust	109	86	62	48	46
Northern Trust	42	35	22	27	19
South Eastern Trust	34	46	28	15	14
Southern Trust	14	16	15	11	10
Western Trust	22	20	11	15	7
Total	221	203	138	116	96

Table 6.5: MRSA bacteraemias patient episodes for each financial year by HSC trust. Source: Public Health Agency: *S. aureus bacteraemia* Surveillance Quarterly report (Q1 2012)

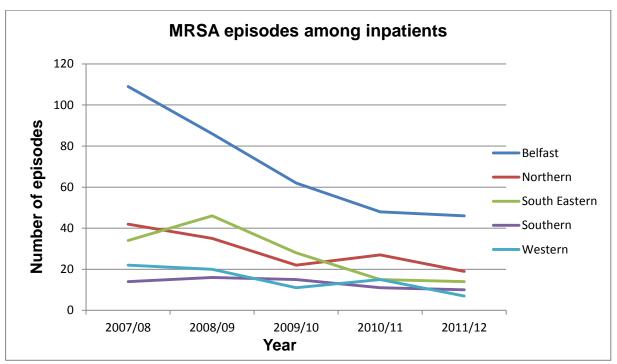


Figure 6.6: Trends in *MRSA* episodes for inpatients by Trust.

Note: These are number of cases and do not take into account bed numbers by Trust

6.5.3 Previous RQIA Reviews of Regional Standards for Governance

In 2011 RQIA carried out a programme of announced and unannounced inspections of trusts based on the Regional Healthcare Hygiene and Cleanliness Standards. The announced inspections (one in each trust) focused on the first standard which relates to organisational systems and governance. Each trust was asked to complete a self-assessment and provide evidence in relation to this standard. Validation was carried out through inspections in each trust by the RQIA Infection Prevention/Hygiene Team.

These inspections focused on areas including:

- policies and procedures in relation to key hygiene and cleanliness issues
- · communication of policies and procedures
- roles and responsibilities for hygiene and cleanliness issues
- internal monitoring arrangements and arrangements to address issues identified through monitoring.

The inspections concluded that each trust had organisational systems and governance systems in place to comply with standard one of the Regional Healthcare Hygiene and Cleanliness Standards, at the time of the inspections. Trusts had processes in place to provide a message to staff that health care associated infections and cleanliness is "everybody's business". This has been taken forward in a "Board to Ward" approach. However, inspections found that in some instances this needed to be more firmly embedded at ward level.

Where improvement was required, recommendations were made for each trust and were included in the reports of the inspections which are available on the RQIA website.

The review team recommend that trusts review their governance arrangements in accordance with the National Institute for Health and Clinical Excellence (NICE), Quality Improvement Guide, Prevention and Control of Healthcare Associated Infections. The statements within this improvement guide aim to help build on previous guidance to improve the quality of care and practice over and above current standards. The quality improvement statements contained in the guidance describe excellence in care and practice to prevent and control healthcare associated infections.

6.5.4 Neonatal Units

The infection prevention and control arrangements and precautions for neonatal units were considered at specific meetings held between members of the review team and relevant trust staff.

The review team noted that there were systems in place to ensure that neonatal units were included in trust action plans on infection prevention and control. Neonatal units were included in programmes of hand hygiene and environmental cleanliness audits. Trust infection prevention and control staff visited the units and provided advice on relevant issues such as isolation. The frequency of these visits varied from once a week to three times a week. When concerns were raised regarding cases of pseudomonas the review team noted that there was rapid involvement of infection prevention and control teams.

The review team was advised by trusts that various initiatives aimed at reducing the risk of healthcare associated infection such as the strengthening of aseptic non touch technique (ANTT) for all aseptic procedures and monitoring of central venous catheter infections had been introduced. Discussions with trusts and review of documentation supplied indicated that there are variations in the introduction of high impact interventions (HII) or care bundles. These are evidence based care processes, related to key clinical procedures that have been shown to reduce the risk of infection if performed appropriately.

The review team recommends that trusts should ensure that high impact interventions related to key clinical procedures are implemented and assured using a standardised common approach across all neonatal units.

In 2011, Altnagelvin NICU clinical team was trained in ANTT for the insertion and management of peripheral lines. The purpose of this technique is to reduce the risk of blood stream infections. In RJMS neonatal unit, a specific initiative was established to prevent infection related to the use of central lines in babies. This involved clinical and infection prevention and control staff. Actions put in place included close monitoring of rates of line infection, observational studies and audit of practice, training on ANTT, education sessions for staff and changes in infusion fluids used.

From meetings with trust staff and visits to the units the review team found that there were variations in practice in relation to: the decontamination of specialist equipment; isolation; environmental cleaning; neonatal clinical and care practice and the preparation, storage and use of breast milk and specialised powdered infant formula.

The review team concluded that there was a strong focus on the need for good infection prevention and control in neonatal units in all trusts but that there were some differences in practice.

On 30 January 2012, the Minister for Health, Social Services and Public Safety asked RQIA to facilitate the development of a range of specialised audit tools with expert public health input from the PHA. The Minister in his statement outlined that these tools should provide an assurance of the standards of infection prevention control within neonatal units and other augmented care settings. A working group has been set up by RQIA and the first tranche of these tools has been developed. These are currently being piloted and will be sent out for wider consultation by early June 2012.

6.6 Governance Arrangements in Relation to the Reporting and Follow-up of Incidents

The arrangements for the reporting of adverse incidents are set out in DHSSPS circular **HSC (SQSD) 08/2010**: "Phase 2 – Learning from Adverse Incidents and Near Misses reported by HSC Organisations and Family Practitioner Services". Organisations are required to report serious adverse incidents (SAIs) to the HSCB. Following the distribution of this circular, the HSCB and the PHA issued operational guidance which defined the incidents which should be reported under these arrangements. The criteria set out includes "unexpected serious risk to a service user..." which would apply to the outbreaks which occurred.

The review team found that the Western Trust submitted an SAI form to the HSCB on 14 December 2011 in relation to the declaration of an outbreak at Altnagelvin neonatal unit. The Belfast Trust submitted an Early Alert to DHSSPS on 17 January 2012 and an SAI form to the HSCB on 18 January 2012 following the declaration of an outbreak at RJMS neonatal unit.

Following the submission of an SAI, organisations are required to carry out an investigation into the circumstances relating to the incident and to identify points for learning.

The Western Trust has provided a copy of the report of the trust investigation to the review team. The Belfast Trust commissioned a root cause analysis, with independent membership, following the outbreak and has provided a copy of this report to the review team also.

The review team has concluded that both the Western Trust and the Belfast Trust fulfilled their responsibilities in relation to the reporting of SAIs after declaration of outbreaks in the neonatal units, in line with agreed governance procedures.

6.7 Recommendations in Relation to Governance

The review team recommends the following actions, having reviewed the effectiveness of governance arrangements in relation to the outbreaks and incidents of pseudomonas:

- Trusts should establish arrangements for independent validation of their selfassessment processes for water management compliance with statutory requirements and guidance.
- Trusts should maintain an evidence file of compliance with L8 and HTM 04-01.
- Trusts should maintain up -to -date registers of all those with named responsibilities under Approved Code of Practice L8 and that each is provided with written authorisation to carry out their statutory functions in water management.
- Trusts should ensure that their written schemes for water management are kept up to date, to reflect changes in procedures and facilities.
- Trust should review the training needs of staff with prescribed functions in water management and ensure appropriate accredited training is provided, when required.
- Trusts should develop Water Safety Plans for Legionella, Pseudomonads and other opportunistic water pathogens as recommended in Annex A (2) of the DHSSPS Circular HSS (MD) 16/2012 issued on 30 April 2012.
- Trusts should develop an annual action plan for water management which should be submitted to Trust Board for approval.
- Trusts should review their governance arrangements for infection prevention and control in accordance with the NICE Quality Improvement Guide: "Prevention and Control of Healthcare Associated Infections".
- The review team recommends that trusts should ensure that high impact interventions related to key clinical procedures are implemented and assured using a standardised common approach across all neonatal units.

7. Communication

To review the effectiveness of the communication between the DHSSPS, the HSCB, the PHA, and the five health and social care trusts in respect of all relevant information and communications on the pseudomonas bacterium

7.1 Introduction

Effective communications are essential, within and between organisations, to ensure delivery of a rapid and co-ordinated response to incidents of communicable disease.

The review team has examined the arrangements in place for the collection and dissemination of information about infectious diseases in hospitals at the time of the pseudomonas incidents. Specific details about what information was shared between organisations was requested, to determine what was known at the time key decisions were taken. The co-ordination and communication arrangements across organisations following the declaration of the outbreaks has also been considered.

7.2 Effectiveness of the General Arrangements for the Communication of Information about Infectious Diseases within Northern Ireland

A number of established systems are in place for the collection and dissemination of information on communicable diseases in Northern Ireland. Examples of these include:

- a) Thirty-five diseases are subject to statutory notification by doctors to the Director of Public Health at the PHA. The purpose of this system is to ensure that there is a rapid response when these diseases are detected or outbreaks are suspected. The PHA publishes the number of notifications of these diseases on its website.¹ Pseudomonas is not subject to statutory notification through this system.
- b) The Health Protection Agency (HPA) co-ordinates a voluntary surveillance database for bacteraemias and fungaemias (infections of the blood system) across England, Wales and Northern Ireland. Pseudomonas infections of the blood are included in this system.
- c) Enhanced surveillance arrangements have been established for infections caused by *Clostridium difficile* and *Staphylococcus aureus* (MRSA and MSSA). PHA published quarterly surveillance bulletins about these infections on its website².. PHA also circulates monthly monitoring reports across health and social care for *Clostridium difficile* and MRSA. A number of additional blood stream infections (including pseudomonas) are included in regional surveillance programmes delivered by PHA.

www.publichealth.hscni.net/directorate-public-health/health-protection/notifiications-infectious-diseases

www.publichealth.hscni.net

- d) The HPA hold weekly teleconferences across the United Kingdom for health protection organisations to share intelligence on emerging issues in relation to infectious diseases. PHA participates in these on a regular basis.
- e) The PHA has issued health protection service bulletins: 'Transmit' since June 2010 for health protection professionals in Northern Ireland. Eight editions of Transmit were issued in 2011. These bulletins provide information about trends in particular diseases and health protection issues. The bulletins are available on the PHA website³.
- f) The PHA established a duty room in 2009 to act as a regional hub for the collection and assessment of information about infectious diseases in Northern Ireland including reports, notifications and laboratory data. The duty room is staffed by a team of Health Protection staff including a duty officer, a Speciality Registrar and /or nurse, with a Consultant in Health Protection overseeing the service on a daily basis. An on-call system is in place outside normal working hours thereby providing a 24 hour 7 day a week service including bank holiday periods.
- g) Trusts have established local arrangements for the dissemination of information about infectious diseases within their organisations. For example, the Western Trust places relevant information on a shared database which can be accessed by relevant professionals and the Southern Trust holds daily briefing meetings to share intelligence and populates an HCAI e-dashboard accessible by all clinical staff.

The review team has considered the effectiveness of the existing communication systems in the context of the recent pseudomonas incidents.

The Western Trust advised the PHA through the regional on-call arrangements on 12 December 2011, of the outbreak at Altnagelvin neonatal unit when it was formally declared. Thereafter, the trust sent a daily update by email to the PHA Duty Room within which details of the control measures, including the use of sterile water, were reported. Information about this incident was then shared within the PHA. The medical director at the Western Trust also informed the DHSSPS about this incident on 13 December 2011.

The PHA was aware, through an exchange of information at the Western Trust incident team meeting, that there were two cases of pseudomonas infection in the neonatal unit at RJMS in December 2011. The PHA contacted the IPC lead doctor for the Belfast Trust on 14 December 2011 in relation to these cases as had been agreed at the Western Trust Incident Control meeting. The DHSSPS was also informed about these cases. On 15 December 2011, preliminary typing results indicated that the two cases had different strains of pseudomonas. The Belfast Trust advised the PHA of this finding on that day.

On 17 January 2012, the Belfast Trust advised the PHA that an outbreak had been declared at RJMS Neonatal Unit.

³ www.publichealth.hscni.net/publications/transmit-health-protection-service-bulletin-2012-issue-1

The Northern and South Eastern trusts advised the review team they were not aware that an outbreak of pseudomonas had occurred at Altnagelvin neonatal unit, prior to the declaration of the outbreak at RJMS neonatal unit on 17 January 2012. They advised that they first became aware of the situation through the media.

Possible reasons as to why this information was not known by the other trusts were considered by the review team to identify any gaps in current communication processes.

- 1. Trusts advised the review team that it would not be common practice for them to advise other trusts about incidents in their area, unless there was a need to share details for particular clinical or health protection reasons. For example, relevant information was shared relating to the clinical care of a baby who had a diagnosis of pseudomonas when the baby was transferred between Altnagelvin and RJMS neonatal units on 2 December 2011. They considered that the PHA would have the role of sharing relevant information.
- 2. PHA advised the review team that the duty room can be informed of unusual events, which have occurred in relation to infectious diseases in trusts in advance of outbreaks being declared, but this did not occur in relation to these incidents.
- 3. PHA advised the review team that DHSSPS had confirmed that they would be issuing an early letter to the service following the incident at Altnagelvin and provided input to the drafting of the circular. They therefore did not issue a separate communication.
- 4. There was local media coverage in the Western Trust area related to the outbreak at Altnagelvin neonatal unit in December 2011, but this was not picked up outside the trust area.
- 5. The DHSSPS circular of 22 December 2011 referred to the September 2010 circular, and specifically the purpose of that earlier communication 'to raise awareness of potential cross infection from taps and basins'. It referred to 'reports from English NHS Trusts and Public Health Wales concerning outbreaks of infection with Pseudomonads'. The December 22 letter states 'similar events have recently been reported in Northern Ireland.' This letter also emphasised that augmented care environments including neonatal critical care 'were particularly at risk'. The review team was advised that it was decided that the circular should refer to augmented care wards (for example high dependency, adult and neonatal critical care) rather than specifically to neonatal units following an assessment of the information available at that time and the known risks.
- 6. Information about the incident in Altnagelvin was shared at a meeting of the PHA Regional Health Protection Advisory Forum on 5 January 2012. Not all trusts were represented. The notes issued after the meeting did advise that the "Western Trust had five bacteraemias (which included the 3 babies infected with pseudomonas) among neonates over recent weeks" but did not specifically mention pseudomonas.

The review team was made aware that information about a pseudomonas incident in a neonatal unit in England, with a possible link to sensor taps, was shared at a weekly HPA teleconference in mid-December 2011.

This was passed on by the PHA health protection consultant who took part in the teleconference to the PHA health protection consultant who was representing the PHA on the Western Trust's Incident Control Team. However, there is not a routine system for sharing of this information by the PHA with other organisations.

The review team has concluded that there is a gap in the current arrangements for communication of early intelligence about infectious disease events across organisations in Northern Ireland. A valuable additional resource for sharing of national and regional intelligence to health protection professionals across Northern Ireland would be a weekly bulletin, in addition to the PHA Transmit bulletin, which is published less frequently.

Such bulletins are produced by local HPA offices in England and can alert health protection professionals to emerging issues. The bulletin could include relevant information from the HPA weekly report. The success of such a bulletin depends on the sharing of information about unusual events at local level and effective systems to link into intelligence at national and international level.

The review team recommends that the PHA establishes a weekly health protection alert bulletin for health protection professionals across Northern Ireland.

It is also recommended that all organisations review their systems to ensure that any unusual incidents or intelligence related to infectious diseases are shared promptly with the PHA duty room so that they can be considered for wider dissemination through a weekly bulletin, or more rapidly, if necessary.

In response to a request from the review team, the PHA has recommended that types of incidents that may fall into this category would be:

- Increase in identifications/reports of a particular infection (a single report may be relevant)
- Confirmed as likely to be a true increase
- Increase noted over a specified time period
- Increase associated with a particular group of patients or a particular ward/area
- Potentially associated with identifiable risks
- Displaying potential and /or multiple resistance patterns
- Affecting particular numbers and or groups of staff
- · Require input from PHA for risk assessment/management
- Reviewed and assessed locally and agreed to be reported to PHA
- Other incidents/events identified by HSC

The PHA indicated that they would take forward discussion of this proposed list with HSC colleagues.

7.3 Effectiveness of the Communication between Organisations about the Outbreaks and Incidents of Pseudomonas from December 2011 up to the Declaration of an Outbreak at RJMS Neonatal Unit on 17 January 2012

To help understand the sequence of events leading up to and during the pseudomonas incidents, a timeline of events for each trust was presented in the interim report which has not been replicated here. The review team has sought clarification on a number of these events from relevant organisations to help examine the effectiveness of communication between them during this period.

In particular, the review team has sought clarification as to how and what specific information was transmitted in relation to the outbreak in Althagelvin to members of staff in the Belfast Trust, who were managing the emerging situation there. Clarification has also been sought in relation to what information was known in the Belfast Trust about the case of a baby with pseudomonas in Craigavon Area Hospital who subsequently was found to have the strain of pseudomonas linked to the outbreak in Belfast. The review team has also sought and been provided with clarification by DHSSPS as to the decisions taken in relation to the information provided in circular HSS (MD) 31/2011.

7.3.1 Communication with Belfast Trust about the Outbreak at Altnagelvin Neonatal Unit

The review team has found that information was shared between the Western Trust and Belfast Trust about the situation in Altnagelvin neonatal unit through several contacts and mechanisms.

- a) Relevant information was shared, related to the clinical care of a baby who had a diagnosis of pseudomonas infection, when the baby was transferred between Altnagelvin and RJMS neonatal units on 2 December 2011. The results of blood cultures for this baby were shared immediately between the Altnagelvin laboratory and RJMS when they were reported to be positive for pseudomonas.
- b) Following the declaration of an outbreak at Altnagelvin neonatal unit on 12 December 2011, a paediatric consultant from Altnagelvin contacted a neonatologist at RJMS by telephone the following day. The purpose of this contact was to provide information about the situation in Altnagelvin neonatal unit including the infection control measures in place, and to ask that they, the RJMS team, would communicate with the family of the baby previously transferred to RJMS.

This contact was documented at RJMS and the parents of the baby were informed. During this phone call, the RJMS consultant informed the Altnagelvin consultant that there was a second baby with pseudomonas in the RJMS neonatal unit. This information was passed on at the next meeting of the Western Trust incident team.

There is a difference in recollection between the two consultants as to whether information about the death of a baby during the outbreak was shared. The Altnagelvin consultant advised the Western Trust incident meeting later that day

that she had done this, and this is recorded in the minutes of the meeting. The RJMS consultant does not specifically recall this and his contemporaneous note of the conversation has no reference to this.

- c) On 14 December 2011, there was an exchange of emails between the Western Trust IPC Team and the Belfast Trust IPC Team to advise that there had been an outbreak at the neonatal unit, and that a sink had been identified as a possible cause. The Western Trust offered an opportunity to telephone back for more details. The email in response from Belfast indicated that the IPC team was already aware of the incident following the telephone call between the consultants on the previous day. A subsequent email within the Belfast Trust referred to an environmental source, rather than a sink. In a following email to the neonatal unit this was not mentioned.
- d) On 14 December 2011, a PHA consultant in health protection contacted the Belfast Trust IPC Lead doctor by telephone, having learned about a second baby with pseudomonas in RJMS neonatal unit through attending the Western Trust incident team on the previous day. It was agreed at the Western Trust Incident Control meeting that this action would be taken forward by PHA. The Belfast Trust IPC lead doctor agreed to find out more information and phoned back later that day. She advised that typing had been requested. There is a difference in recollection as to what information was shared during these telephone calls and also as to whether a Root Cause Analysis or reporting an SAI was advised. The PHA consultant recalls providing information about the outbreak, and that a sink was a possible cause, but the Belfast Trust IPC lead doctor has no recollection of this. Both consultants advised that there was no information provided in relation to the use of sterile water for nappy changes. The Belfast Trust IPC Lead doctor contacted the PHA consultant on 15 December 2011 to advise that the strains of pseudomonas affecting the two babies were different. The second case in Belfast was therefore assumed to be sporadic.
- e) On 16 December 2011 some information was shared at a performance meeting on HCAIs involving HSCB, PHA and Belfast Trust in relation to the pseudomonas incidents. There are differences in recollection as to what information was shared and this was not recorded in the action notes of the meeting.
- f) On 5 January 2012 the outbreak at Altnagelvin was highlighted by PHA at a regional meeting at which Belfast Trust representatives were present. Specific issues mentioned were not recorded in the draft notes of the meeting and the review team understands that those present from Belfast were not subsequently involved in decisions prior to the declaration of an outbreak.

The review team has concluded that appropriate information was shared between the clinical team at Altnagelvin neonatal unit and the RJMS neonatal unit in relation to the care of the baby who was transferred between the two units. Appropriate information was also communicated to the parents of the baby who had been transferred so that they would be aware that there was an outbreak in Altnagelvin.

Belfast IPC staff were made aware that there was an outbreak at Altnagelvin neonatal unit though a telephone call between clinicians, an exchange of emails between IPC teams, and a telephone call by a PHA Health Protection consultant. However, the review team has found that in early January 2012, there was not a clear understanding by the IPC Team in the Belfast Trust as to the circumstances leading to the outbreak at Altnagelvin or the measures put in place to control the outbreak.

In particular, it was not known that the outbreak had been caused by contaminated water from a tap which had subsequently been replaced or that the use of sterile water for nappy changes had been adopted as one of the control measures.

The review team has found that there were differences in recollection as to what information was shared about the situation at Altnagelvin neonatal units during telephone calls and at meetings. Information shared in emails was subsequently not forwarded in full when being passed on within the Belfast Trust, which impacted on the clarity of the intended message. Abridged records of meetings did not provide much detail of what had happened.

7.3.2 Communication with Belfast Trust in Relation to a Baby in Craigavon Neonatal Unit who had been Diagnosed with *Pseudomonas aeruginosa* Infection

As stated in the interim report, the review team was advised that the Belfast Trust became aware on 10 January 2012 that a baby in Craigavon Neonatal Unit had an infection caused by pseudomonas. At that time the Southern Trust was not aware that there had been an outbreak in Altnagelvin Hospital or that there had been another case in Belfast neonatal unit in December 2011.

The baby in Craigavon neonatal unit had been born in RJMS Neonatal unit and was transferred to Craigavon Neonatal Unit on 23 December 2011. The baby had a positive blood culture for pseudomonas on 29 December 2011. At that time it was not normal practice to inform a transferring unit, in this case, RJMS neonatal unit of a positive pseudomonas bacteraemia.

The review team has sought and been provided with further clarification in relation to the communication of information in relation to this baby.

The baby was transferred to the Royal Belfast Hospital for Sick Children (RBHSC) for day surgery. In line with standard practice, the neonatal nursing transfer summary and the neonatal medical discharge summary noted confirmed pseudomonas infection. This documentation accompanied the baby to RBHSC.

The transfer co-ordinator who arranged the transfer of the baby shared the information with the clinical team in the RJMS Neonatal Unit that the baby had pseudomonas. This information was shared with a medical microbiologist in Belfast.

The Belfast medical microbiologist contacted the laboratory at Craigavon Area Hospital and spoke to a biomedical scientist who provided information about laboratory results for this baby.

The Belfast microbiologist has advised the review team that she was told that a gram negative screen and a separate MRSA screen had been carried out and that the results were negative. The Belfast medical microbiologist's understanding was that the screening for gram negative organisms would include pseudomonas.

The Southern Trust has advised that the biomedical scientist would have no knowledge regarding screening practices at Craigavon Neonatal Unit. The consultant microbiologist at Craigavon Area Hospital was not contacted at that time. The Southern Trust has confirmed that the screening for babies transferred to the neonatal unit at that time was MRSA (for gram positive bacteria) and Enterobacter (for multi-resistant gram negative bacteria).

The Belfast Trust advised the review team that, from the information provided in the telephone call, the Belfast microbiologist concluded that the baby with pseudomonas infection had screened negative from pseudomonas at the time of transfer from Belfast neonatal unit to Craigavon neonatal unit in December 2011, and that it was probable that the pseudomonas infection had been acquired at Craigavon. Subsequently, typing results confirmed that the baby had the strain of pseudomonas associated with Belfast.

The review team has concluded that there was a misunderstanding in Belfast about the information provided during this communication in relation to the screening arrangements for babies transferred to Craigavon neonatal unit.

7.3.3 Information Provided in Circular HSS (MD) 31/2011

Following the publication of the interim report, the review team asked DHSSPS to provide further clarification on the decisions taken to issue and on the content of Circular HSS (MD) 312/2011 on 22 December 2011. This was discussed at a meeting between members of the review team and DHSSPS.

The review team was advised that DHSSPS became aware that there was an outbreak at Altnagelvin neonatal unit through a telephone call from the Western Trust Medical Director to the Deputy Chief Medical Officer on the morning of 13 December 2011. Information about the babies affected and the measures being taken to investigate and control the outbreak was communicated effectively through this telephone call. A subsequent briefing note prepared for the Minister that day clearly described the situation in Altnagelvin.

On the evening of 13 December 2011, further information was provided by the Western Trust after the trust incident team meeting, about a range of control measures which had been put in place. This included the use of sterile water for nappy changes.'

The Western Trust also advised that another baby born in RJMS neonatal unit had pseudomonas. This information was shared that evening with the Chief Medical Officer. As the two babies were being cared for in adjacent cots, the CMO's initial concern, on the limited information available, was that cross-infection had occurred. He also asked Departmental colleagues for advice as to whether he should re-issue Circular HSS(MD) 34/2010.

On 14 December 2011, two DHSSPS Medical Officers were asked to prepare a draft circular and they met that afternoon to consider the possible content. They considered that they would require further information to inform the content of the circular and contacted the PHA that afternoon. They were provided with information about the situation in Altnagelvin including that a sink and tap had tested positive for pseudomonas. They were also advised as to the measures which were being put in place to manage the outbreak. They subsequently advised the CMO by email that:

"while a joint communication from CMO and HEIG may be required, there is still sufficient uncertainty around this incident to be clear about the content and nature of the recommended intervention. Obviously as this is an evolving situation, we will keep in close contact with PHA and Trust colleagues to inform the content and optimum timing of such a letter."

The DHSSPS has advised that content of the letter was decided between medical and estates teams at DHSSPS with input from the PHA. It was shared in draft with the Medical Director of the Western Trust for comment prior to issue. The circular was issued, given the possible implications of the outbreak in Altnagelvin, as it was considered important to reinforce and reiterate the advice which had been issued in the previous circulars. The decision to not specifically mention Altnagelvin neonatal unit was also influenced by a recognised need to protect confidentiality of the families affected. The DHSSPS however advised the review team that their primary concern was to ensure that the trusts understood that the guidance applied to all augmented care units in all trusts.

Over the next week the DHSSPS received regular updates on the situation in Altnagelvin and was also advised that the two babies in RJMS neonatal unit had different strains of pseudomonas and that the baby who had been born there was therefore considered to be a sporadic case. The results of typing of human and environmental strains of pseudomonas from Altnagelvin to see if there was a causal link between infections and the contaminated tap and sink, became available, later on 22 December 2011, after the circular had been issued.

DHSSPS advised the review team that it was understood that, at that time, the use of sterile water was a pragmatic response to the issue faced in Altnagelvin as a precautionary measure while work was undertaken on the water system which had been identified as a potential source of the infection on samples from one tap and sink in the unit. This was not therefore included in the circular. At that time there was no indication that this was required in any other units.

DHSSPS also advised that in December 2011, the HPA website contained little information on pseudomonas and there was no national guidance available to inform the correct response. It was also unclear what the appropriate action should be if a tap should be considered as the source of the infection.

The circular issued did not provide a direct reference to an outbreak having occurred in a neonatal unit it in Northern Ireland, or refer specifically to the situation in Altnagelvin. It did refer to recent events having occurred in Northern Ireland linked to pseudomonas.

The circular stated that:

"The purpose of this letter is to remind you of the potential infection risks posed by water systems in healthcare facilities and to reinforce important messages contained in earlier communications."

Trusts advised the review team that they did not perceive the circular as requiring immediate action as they considered that they had acted on the advice which had been contained in the circulars issued previously. The circular was distributed widely on receipt before the Christmas holiday period and decisions were taken to discuss it at the next meetings of relevant groups in relation to the other actions.

Three trusts were not aware of the situation in Altnagelvin at that time. The Belfast Trust IPC Team, who were aware that there had been an outbreak of pseudomonas, linked the issue of the circular to the situation in Altnagelvin earlier that month and that there was a known link between pseudomonas and water.

The review team has concluded that it was appropriate to issue a circular at that time following the incident at Altnagelvin. The previous circular in 2010 had been issued after reported incidents of pseudomonas in augmented care settings in England and Wales, linked to hand hygiene stations. This had now happened in Northern Ireland. Whilst the review team recognise that the DHSSPS had only limited information, they issued the circular because of a concern in relation to pseudomonads. That concern was not conveyed to the Trusts who therefore treated it as routine.

However, the review team has also concluded that it is not possible to determine if the course of events would have been materially altered if the wording of the circular had been more explicit as the trusts considered that they had already acted on the information contained from the earlier circulars.

7.3.4 Recommendation

The review team considers that the analysis of the effectiveness of communication between organisations in relation to these incidents highlights the need for agreed arrangements for sharing key information in writing to be put in place. It is recommended that all organisations review their arrangements for sharing and documenting information received in relation to infectious disease incidents in the light of these findings.

7.4 Effectiveness of the Communication and the Co-ordination Arrangements between Organisations following the Declaration of an Outbreak at RJMS Neonatal Unit on 17 January 2012 up to 31 January 2012

On 17 January 2012, following the declaration of an outbreak at RJMS Neonatal Unit, the PHA was informed by Belfast Trust of the outbreak. The PHA agreed with measures put in place by Belfast and offered support and advice including advising contact with Altnagelvin.

The Belfast Trust issued an early alert notice to the DHSSPS about the incident, and advised that two babies had been confirmed with the same strain of pseudomonas of whom one had died. The trust was awaiting results on two other babies one of whom had died. Admissions to the unit were to be restricted.

During the period from 17 January 2012 until 31 January 2012 (the last date of the period subject to this review), there was an extensive period of activity relating to the incidents involving all HSC organisations in Northern Ireland. Many members of staff were involved during this period across the whole HSC system. A high level outline of the actions taken was set out in the chronology sections of the interim report.

The review team has considered the evidence submitted by organisations involved and discussed with them the co-ordination and communication arrangements which were put in place. The aim was to identify any lessons for managing incidents in the future.

The review team found that organisations put in place their local arrangements for managing the incidents. The impact on each organisation was very different depending on the circumstances relevant to their situation.

The Belfast Trust had established an outbreak control team to manage the outbreak which had been declared. By this date, the outbreak in the Western Trust had been controlled, and they, together with other trusts, established incident management arrangements to take forward actions which were being advised by the regional organisations.

During the period 20 to 22 January 2012, the HSCB led the combined response of the HSCB/PHA/BSO, as the main issue at that time was considered to be the requirement to manage available neonatal cot capacity due to the closure of the NICU room at the RJMS neonatal unit. On 22 January 2012, PHA took over the lead role for this combined response as it was considered that the issues were primarily related to public health, rather than service delivery. On 22 January 2012, HSCB/PHA/Business Services Organisation (BSO) formally activated their joint response plan to incidents. An emergency operations centre was established and plans were put in place to develop a regional epidemiological investigation.

The response to the incident also had a major impact at government level, with the Minister, CMO and colleagues actively engaged in providing briefings to the Northern Ireland Assembly and media responses. The DHSSPS communicated with the HPA in relation to the content of circulars and advice on managing the situation.

The review team has concluded that there was active engagement by all organisations during this period to ensure an effective response to the incidents and the emerging situation.

The review team has identified a number of areas for consideration in relation to communication and co-ordination in the development of future plans for incident management.

1. Clarification of Roles When Responding to Regional Infectious Disease Incidents

Through discussion with organisations the review team found that there was not a shared understanding of the roles of the different organisations in the co-ordination of the response after 17 January 2012.

During this period, the Belfast Trust had responsibility for managing the outbreak at RJMS neonatal unit and established an outbreak control team. Other trusts set in place local arrangements for managing the situation in their organisations. The situation had significant regional implications for all organisations, so the HSCB, PHA and BSO activated their joint plan for their response to a regional incident.

There was some evidence of confusion as to the responsibility for levels of decision making, and as to whether the HSCB/PHA were acting in a co-ordination role across organisations, together with providing advice to a local outbreak team, or in a Silver Command type role, which may be put in place for a regionally managed incident.

2. Development of Joint Plans to Respond to a Regional Outbreak

The review team found that individual organisations had plans in place to manage outbreaks and emergency incidents. The HSCB/PHA/BSO had established a joint plan for their organisations to work together when they respond to an incident.

The review team was advised that there is not a joint plan for a regional response which involves all the organisations concerned in the management of outbreaks affecting more than one organisation, and recommends that this should be developed.

3. Organisation of Teleconferences

During this period a series of daily teleconferences were established by the HSCB/PHA to assist in the co-ordination of the response. Additional teleconferences were held to co-ordinate estates issues, and in particular in relation to the programme of replacement of taps. The PHA and HSCB explained that the purpose and overall strategy of these teleconferences was to co-ordinate actions across the system and they considered that each one had a well-defined agenda.

Nevertheless trusts had mixed views about the effectiveness of the teleconferences for communication and co-ordination. This may in part reflect the particular challenges they were facing at that time with some trusts looking for guidance and others, information as to what was happening across the system. At the start, some organisations were unclear as to who should take part. The time involved was generally considered to be excessive by trusts. The overall perception was that the organisation of the teleconferences improved over the period of the response.

There was a perception by some trust clinical staff that they should participate in all the regional teleconferences, as at times discussions took place at that level which could directly impact on the information being provided to individual families under their care.

The review team recommends that guidelines are developed for the organisation of, and participation in, regional teleconferences for future incidents.

7.5 Recommendations in Relation to Communication

The review team recommends the following actions having reviewed the effectiveness of communication arrangements in relation to the outbreaks and incidents of pseudomonas.

- The Public Health Agency should establish a weekly health protection alert bulletin for health protection professionals across Northern Ireland.
- All HSC organisations should review their systems to ensure that any unusual incidents or intelligence related to infectious diseases are promptly shared with the PHA duty room.
- All organisations should review their arrangements for sharing and documenting information received in relation to infectious disease incidents.
- A joint plan across relevant organisations for the regional response to the management of outbreaks, affecting more than one organisation, should be developed, which clearly identifies the roles of each organisation.
- Guidelines should be developed for the organisation of, and participation in, regional teleconferences for future incidents.

8. Findings in Relation to Other Matters

8.1 The Impact on Staff

Members of the review team have met many clinical and managerial staff during the course of this review. In all organisations we were greeted with professionalism, courtesy and an openness which we greatly appreciated.

We found that there was a universal desire to understand the causes of the outbreaks, to manage the consequences and to find reliable methods of prevention. We recognise that the review has almost certainly contributed to the stresses endured by staff.

During our meetings with parents, most indicated that they had perceived the impact which the incidents were having on the staff who were caring for their babies.

From our engagement with staff, it was clear to the members of the review team that staff within organisations have been deeply affected by the consequences of the outbreaks of pseudomonas. This impact has been felt by the clinical staff who were providing the direct care of the patients and also by staff providing essential functions such as domestic services, infection control and managers at all levels.

The review team has discussed with organisations, the arrangements in place to support staff at this very difficult time for them. Organisations have systems in place to provide support but did advise the review team that these are not always accessed.

The review team recommends that all organisations review their arrangements for supporting staff during incidents including outbreaks and ensure that incident plans include provision for support for staff both during and after incidents.

8.2 Use of Sterile Water for Washing Babies

In the Interim Report of the RQIA Review Team, it was recommended that sterile water should be used when washing all babies in neonatal care (Levels 1, 2 and 3) pending early consideration of the Department of Health (DoH), England guidance issued on 30 March 2012.

On 30 April 2012, the DHSSPS issued a Joint Professional Letter HSS (MD) 16/2012 following consideration of the guidance issued in England. The Joint Professional Letters sets out the policy on using sterile water, as is the recommendation of the interim report.

The Review Team has been made aware of concerns that this policy has implications for instructions for parents on bathing babies prior to bringing their baby home, given that babies will experience contact with tap water as soon as they return home.

The Review Team recognises that the babies at highest risk from acquiring pseudomonas from tap water are those whose skin is underdeveloped and those who have intravenous cannulae in situ.

In the light of the emerging evidence as to the risks associated with particular tap components which may facilitate design solutions, and the intelligence gained from the water sampling programme, the review team recognises that the risks associated with using tap water for bathing babies need to be kept under review. It may in future be reasonable to recommend that babies with no identified skin pathology who weigh more than 1,500 grams and who do not have intravenous infusions might safely be bathed in warm water from the tap, provided there is no evidence of contamination of the water in that unit.

8.3 Update on Other Investigations and Processes

The interim report of this review referred to a number of other important exercises which are underway related to the terms of reference of this review. During the second stage, the review team has been provided with further information about these processes.

- A subgroup of the UK Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) has advised the review group that work is now underway to develop guidance on the management of infections in neonatal units.
- The PHA has provided the review team with a further interim report setting out the current position of the epidemiological investigation of the pseudomonas incidents in Northern Ireland. The findings to date do not materially affect the position as described in the Interim Report.
- Belfast Trust has provided the review team with a copy of the final report of the root cause analysis, carried out by a team which included independent expert advisors, into the pseudomonas outbreak at the RJMS neonatal unit.
- Western Trust has provided the review team with a copy of the report of an Incident Review which was carried out by the trust in relation to the outbreak at the Altnagelvin neonatal unit.
- Southern Trust has completed an internal review chaired by a non-executive director which has been shared with the trust board.

8.3.1 Investigation of Pseudomonas aeruginosa on Biofilms in Water Tap Assemblies from Neonatal Units in Northern Ireland

In the interim report attention was drawn to a study being carried out by the Health Protection Agency (HPA) on behalf of the Northern Ireland Adverse Incident Centre to examine the taps removed after the incidents of pseudomonas at neonatal units in Northern Ireland.

The review team has been provided with a final draft of the report of this study to inform the preparation of this report. The Executive Summary of the report is set out overleaf. This study has reached important conclusions as to the link between pseudomonas and the components called rosettes in the taps which were removed from the neonatal units. The study also reports that the strains of pseudomonas which led to infection of babies have been identified from the tap components which were analysed.

The authors of the report of the study recommend that further work should determine whether tap outlets used in neonatal units can be redesigned such that complex rosettes are not necessary and manufacturers should investigate the possibility of making the tap outlet removable for decontamination by autoclaving. The review team strongly endorse these recommendations.

Executive Summary from the Investigation of Pseudomonas aeruginosa on Biofilms in Water Tap Assemblies from Neonatal Units in Northern Ireland

"A study has been carried out to assess the presence of Pseudomonas aeruginosa biofilms on various tap assembly components from neonatal wards in Northern Island following three fatal cases of Pseudomonas aeruginosa bacteraemia that occurred in neonatal units in Northern Ireland in December 2011 and January 2012.

Tap assemblies (n=30) and rosettes (n=8) were removed from the hand wash basins from neonatal units in Northern Ireland and couriered to HPA Porton Down, Salisbury. Tap assemblies were dismantled into separate and discrete components (n=494). Each component was assessed for the presence of microbial contamination by enumerating total aerobic colony counts and Pseudomonas aeruginosa colony counts using non-selective and selective agars. P. aeruginosa isolates recovered from tap components were typed by the variable number tandem repeat (VNTR) technique at HPA Colindale. Selected tap components were also subjected to microscopy to visualise the presence of biofilm using fluorescence and scanning electron microscopy.

There was little correlation (r=0.33) between the aerobic colony count and P. aeruginosa presence or counts indicating that the aerobic colony count could not reliably be used to predict the presence of P. aeruginosa.

The highest aerobic colony counts were associated with the mixer and solenoid whilst the highest P. aeruginosa counts were recovered from the rosettes and associated components, indicating that P. aeruginosa has a preference to colonise different tap location, e.g. the rosette, metal support collar and surrounding tap body.

The analyses of the rosette components and the rosette complexity, rosette type and rosette material indicated that on average a complex rosette (ie: one with multiple component parts and a higher internal surface area) had a significantly higher expected P. aeruginosa count than a simple rosette. Microscopy identified the presence of biofilm on the rosettes and associated components.

Representative isolates recovered from tap assemblies from Belfast (Royal Jubilee Maternity) and Altnagelvin Hospital neonatal units had VNTR profiles that were consistent with the strains that were recovered from the water samples and those that were recovered from the infected patients.

This study has demonstrated a positive association of *P. aeruginosa* with a complex design of rosette in the tap outlet. Further work should determine whether tap outlets used in neonatal units can be redesigned such that complex rosettes are not necessary and manufacturers should investigate the possibility of making the tap outlet removable for decontamination by autoclaving."

The Belfast Trust advised the review team that they are participating in a trial of new rosette less taps, in conjunction with the Department of Health (DoH) and HPA and is currently in the process of sharing these findings regionally and nationally.

8.4 Recommendations

- All organisations should review their arrangements for supporting staff during incidents including outbreaks and ensure that incident plans include provision for support for staff both during and after incidents.
- The recommendation on using sterile water in the interim report should be kept under review in relation to babies in Level 3 neonatal units (Special Care Baby Units) as new evidence emerges.

9. Overall Conclusions from the Review

On 30 January 2012, RQIA was commissioned by the Minister to carry out an independent review following incidents of infection caused by *Pseudomonas aeruginosa* at neonatal units in Northern Ireland which led to the tragic death of a baby in Altnagelvin Hospital and three babies in Royal Jubilee Maternity Hospital. RQIA established an independent Review Team chaired by Professor Pat Troop. The review was carried out in two phases. This section of the report sets out the conclusions of the review team in relation to each of the Terms of Reference following the completion of both phases.

9.1 To investigate the circumstances contributing to the occurrences of pseudomonas infection in neonatal units from 1 November 2011

The review team has found that four neonatal units in Northern Ireland had incidents of infection or colonisation of babies with *Pseudomonas aeruginosa* during the period between November 2011 and January 2012. In each case the incidents were caused by different strains of the organisms so there was no evidence of direct spread of infection between the units.

The outbreaks of infection at Altnagelvin Hospital and Royal Jubilee Maternity Hospital have been definitively linked to contaminated tap water in the intensive care rooms of the neonatal units. A detailed analysis of the taps and fittings has been carried out by the Health Protection Agency on behalf of DHSSPS. This study has reported that the strains of *Pseudomonas aeruginosa* which caused infection in babies at the two hospitals were also detected from internal components of the taps in the neonatal units. The study has demonstrated a positive association of *Pseudomonas aeruginosa* with a complex design of rosette in the tap outlet. The review team strongly endorses the proposal that further work is carried out on the design of taps to address the problem which has been identified.

The review team concluded that the most likely method of spread of *Pseudomonas* aeruginosa from contaminated taps to babies in Altnagelvin and Royal Jubilee Maternity Hospitals was through the use of tap water for washing babies during nappy changes. The use of tap water in Royal Jubilee Maternity Hospital to defrost breast milk may also have contributed. Invasive procedures are likely to have contributed to the spread of infection when babies had been colonised with the organism on their skin.

The review team concluded that the design and lack of appropriate accommodation for isolation or cleaning equipment in the intensive care unit at Royal Jubilee Maternity Hospital did not facilitate good infection and prevention control practices.

- 9.2 To review the effectiveness of the trusts' management of the occurrences of pseudomonas infection and colonisation within neonatal units, to include:
 - a. The management of the occurrence of pseudomonas infection and colonisation in the neonatal unit in the Western Trust
 - b. The management of the declared outbreak of pseudomonas infection and colonisation in the neonatal unit in the Belfast Trust in January 2012
 - c. The management of any colonised babies in the other neonatal units across Northern Ireland

The review team found that staff in all trusts acted to reduce risks of spread of infection and to investigate why the incidents had occurred. In the interim report of the review, the review team identified a number of key issues which may have impacted on the speed with which measures to control the incidents were put in place.

Information about cases which had occurred in other trusts was not always readily available to inform critical decisions. There was no agreed system for the surveillance of pseudomonas colonisation and infection and this led to delays in sharing of information between trusts. The review team recommended that a surveillance system is established as soon as possible.

Following the identification of single cases of infection with *Pseudomonas aeruginosa*, all trusts, in line with current practice in the rest of the UK, considered the cases to be sporadic. The review team recommended that *Pseudomonas aeruginosa* should be identified as an alert organism for neonatal intensive care and high dependency units, and when identified from a sample from a baby, the taps and sinks in rooms which had been occupied by that baby since birth, should be tested.

Trusts had different approaches to the declaration of outbreaks. This may have led to a delay in putting control measures in place when cases of infection occurred. The review team recommended that an agreed approach is established across all trusts.

Prior to the outbreaks, typing of strains of *Pseudomonas aeruginosa* was carried out in England and it could take several days for results to be available to determine if cases were linked. The review team recommended that arrangements for typing of *Pseudomonas aeruginosa* should be established in Northern Ireland to reduce the risk of delays in identification of related incidents of infection.

During the second phase of the review, the review team sought clarification on the communication of information during the period when the outbreaks and incidents occurred. The findings are set out in this report in relation to Term of Reference 3.

The review team has now concluded that the Belfast Trust, whilst they were aware of the outbreak in Altnagelvin, did not have a clear understanding of the situation nor all the measure taken, when determining what actions to take after blood cultures were diagnosed as positive for pseudomonas on 8 January 2012, from a baby who had died on 6 January 2012. This lack of clarity may have impacted on the decision not to call an outbreak.

Measures were taken at that time including, enhanced infection control and typing of the strain of pseudomonas to determine if there was a link to either of the unrelated cases in December 2011. The review team feels that testing of water could have been considered at this time as an additional measure whilst awaiting the results of typing.

The review team has concluded that appropriate information was shared between the clinical team at Altnagelvin neonatal unit and the RJMS neonatal unit in relation to the care of the baby who was transferred between the two units. Appropriate information was also communicated to the parents of the baby who had been transferred so that they would be aware that there was an outbreak in Altnagelvin.

Belfast IPC staff were made aware that there was an outbreak at Altnagelvin neonatal unit though a telephone call between clinicians, an exchange of emails between IPC teams, and a telephone call by a PHA Health Protection consultant. However, the review team has found that in early January 2012, there was not a clear understanding by the IPC Team in the Belfast Trust as to the circumstances leading to the outbreak at Altnagelvin or the measures put in place to control the outbreak.

In particular, there was not clarity that the outbreak had been caused by contaminated water from a tap which had been replaced or that sterile water for nappy changes had been put in place as one of the control measures.

The review team has found that there were differences in recollection as to what information was shared about the situation at Altnagelvin neonatal unit during telephone calls and at meetings. Information shared in emails was subsequently not forwarded in full when being passed on, which impacted on the clarity of the intended message. Abridged records of meetings did not provide much detail of what had happened.

9.3 To review the effectiveness of the governance arrangements across all five health and social care trusts with regard to the arrangements for the prevention and control of infection and all other relevant issues in their respective neonatal units

The review team considered governance arrangements in each trust in relation to: ensuring action is taken in response to circulars and advices; the management of water distribution systems in hospitals; the prevention and control of infection; and the reporting and follow up of incidents. Information was also sought and received as to the actions taken in relation to circulars and advices relating to water management issued in Northern Ireland since September 2010.

The review team concluded through the evidence submitted and discussion with trust board members and senior managers that all trusts have established systems in place for integrated governance within their respective organisations.

All trusts have systems in place to receive, record, disseminate and follow up action on circulars and advices which are received. Trusts emphasised the importance of having a single point of entry for circulars through the Office of the Chief Executive. The review team was advised by some trusts that they have established specific arrangements to screen and triage action on circulars to ensure that immediate priorities are taken forward.

Some trusts advised that they have reviewed their procedures following the pseudomonas incidents. The review team concluded that trusts recognised the need for good systems to manage the response to circulars and advices and had taken steps to ensure that they had robust systems in place.

In relation to water management, each trust has established a Water Safety Group and appointed a "Responsible Person" for water. Trusts provided evidence of relevant documentation and that training needs analyses for staff had been carried out. Risk assessments for water systems were being carried out. The approach used, and the stage of completion, differed between trusts.

The review team concluded that all trusts recognise the importance of good water management. Following a review of the documentation provided, and meetings with trust staff, the review team has made a number of recommendations to strengthen the arrangements for water management where these are not already in place.

In relation to infection control the review team found that the prevention and control of infection in hospitals is a very high priority for all HSC organisations with regional targets for reductions in infection and close monitoring of performance. There have been significant falls in the number of cases of *Clostridium difficile* and MRSA over the past five years in all trusts although there is a recognised potential for further reductions with a continuing drive to reduce target levels.

In relation to neonatal units the review team concluded that there was a strong focus on the need for good infection control with specific initiatives having been put in place. There were some variations in practices between trusts. The review team has been advised that work, commissioned by the Minister has progressed on the development of specialist audit tools for infection prevention and control in augmented care settings, including neonatal care.

The review team found that the regional Serious Adverse Incident Reporting Arrangements were followed by the Western and Belfast trusts after the declaration of outbreaks in the neonatal units. Trusts carried out investigations following the reporting of incidents in line with regional guidance.

The review team examined documentation provided by trusts relating to actions taken in response to the circulars and advices issued in relation to water management since September 2010. The circulars and advices were processed through the trust mechanisms for recording and dissemination of circulars.

The review team found that all the circulars were considered and, in general, actions were taken to implement guidance, although there were some differences on actions taken between trusts, for example, in relation to the use of alcohol gel following hand washing.

The first circular issued on 15 September 2010 was interpreted as meaning that, if following a risk assessment, there was no evidence of a problem with infection, additional water testing was not required to be put in place. All trusts concluded that they did not have a problem with pseudomonas in neonatal units at that time.

The circular issued on 22 December 2011 was regarded as a reminder for action on the earlier communications on which they had already acted. The circular was promptly circulated to appropriate staff with planned discussion to take place at the next meetings of relevant groups such as Water Safety Groups. Three trusts advised the review group that they were not aware of the local incidents that had taken place and which were referred to in the circular.

The review team has concluded that the circulars were taken forward in keeping with the governance arrangements in each trust. Based on the contents of the circulars, in general, the actions which were taken by the trusts were appropriate, although there were some differences between the decisions taken by different trusts.

9.4 To review the effectiveness of the communication between the DHSSPS, the HSCB, the PHA, and the five health and social care trusts in respect of all relevant information and communications on the pseudomonas bacterium

The review team has reviewed extensive documentation concerning the communication between organisations during the pseudomonas incidents and in relation to the response to the incidents. Meetings have been held with each organisation to clarify issues and to discuss their perceptions of the communications.

The review team has concluded that the effectiveness of communication was not uniform. There were examples of excellent communication, but also of situations where important information was not communicated effectively.

The review team found that formal arrangements for reporting outbreaks to the PHA were followed by the trusts who declared them. Appropriate information was also shared with DHSSPS at those times.

Three trusts advised that they were not aware for several weeks that an outbreak of pseudomonas had taken place in the neonatal unit at Altnagelvin Hospital, indicating that there are not strong informal networks to share information. Trusts also advised that they received limited information as to current issues across the United Kingdom in relation to infectious disease incidents. The review team has concluded that there is a need to establish a weekly infectious disease bulletin to share relevant information about incidents and issues both within Northern Ireland and from the rest of the UK.

The review team found that the communication of information in relation to the clinical care of a baby who was transferred from Altnagelvin to Belfast with pseudomonas infection was exemplary in both trusts. Information was shared with the RJMS neonatal unit when the outbreak in Altnagelvin occurred so that the parents could be made aware of this. This was promptly acted on in Belfast.

The review team has investigated the transmission of information to Belfast Trust in relation to the outbreak in Altnagelvin to determine what information was clearly communicated to Belfast. The review team has concluded that there was not a clear picture in Belfast as to what had taken place in Altnagelvin in relation to the link to contaminated water from a tap or of the control measures which had been put in place.

Information has been provided by respective organisations as to what information was provided and received during several telephone calls between members of staff and at meetings. There are clear differences in recollection, with strongly held views as to whether specific information was shared or not. The review team has concluded that these are genuine differences in recollection and highlight the problems in communicating relevant information solely by telephone or at meetings where it is not recorded in the minutes. Issues were also identified in relation to email communication with interpretation of information shared in subsequent emails changing the original intention of messages. The review team has recommended that all organisations review their arrangements for sharing and documenting information received in relation to infectious disease incidents.

The review team has considered the information provided in Circular HSS (MD) 31/2011. Information was sought and provided by DHSSPS as to the rationale and development of the contents and timing of the circular. This was discussed at a meeting with DHSSPS staff involved in the development of the circular.

At the time it was issued the results of strain typing from Altnagelvin were not known and it was not clear as to which of several actions taken in Altnagelvin had led to the control of the outbreak there. DHSSPS understood that the introduction of sterile water for nappy changes had been a precautionary measure while work was being undertaken on the water system. The circular did not refer directly to the Altnagelvin outbreak in a neonatal unit as it was considered that the advice needed to be given for all augmented care settings and there was a concern that a direct reference to Altnagelvin could impact on patient confidentiality.

The review team found that trusts did not perceive the circular as requiring urgent action as they considered that they had already acted on the previous circulars which were being issued as a reminder. The circular was considered and referred to the next meetings of relevant trust groups.

The review team considers that the lack of general awareness of the situation which had occurred in Altnagelvin, and the perception that the circular was a reminder, are likely to have influenced how the circular was viewed when it was issued. Belfast Trust was aware that there had been an outbreak in Altnagelvin and linked the release of the circular to that incident. Their response to the circular was similar to other trusts.

The review team has concluded that it was appropriate to issue a circular at that time following the incident at Altnagelvin. The previous circular in 2010 had been issued after reported incidents of pseudomonas in augmented care settings in England and Wales, linked to hand hygiene stations. This had now happened in Northern Ireland. Whilst the review team recognise that the DHSSPS had only limited information, they issued the circular because of a concern in relation to pseudomonads. That concern was not conveyed to the Trusts who therefore treated it as routine.

However, the review team has also concluded that it is not possible to determine if the course of events would have been materially altered if the wording of the circular had been more explicit as the trusts considered that they had already acted on the information from the earlier circulars.

The review team also considered communication arrangements across Northern Ireland after the declaration of an outbreak at RJMS neonatal unit. Many staff across all organisations were involved during this period.

The review team found that there was active engagement by all organisations in the response. A number of areas to improve communication were identified.

There is a need to clarify the roles of different organisations when there is a regional response to a communicable disease incident. The review team recommended that there is a joint plan for managing outbreaks affecting more than one organisation.

A main mode of communication during this period was through teleconferences. The review team found that there were mixed views of the effectiveness of these and has recommended that guidelines for teleconferences are developed for use in future incidents. In particular there is a need to ensure that the involvement of clinical staff is limited to occasions when it is essential to the situation as the teleconferences can take them away from clinical duties at a very busy time.

9.5 To examine any other relevant matters which emerge during the course of the review

9.5.1 Neonatal network arrangements in Northern Ireland

The review team found that there is no formal neonatal network across the five neonatal intensive care units and two special care baby units. An informal network exists, but clinical staff informed the team that there are no common protocols in place across the neonatal units. Arrangements to ensure that babies are cared for in the units most appropriate to their needs are not fully developed.

The Neonatal Transfer Service does not operate on a 24 hour basis and alternative arrangements are put in place out-of-hours. The review team considers that this should be reviewed and plans established to expand the service with a goal to move to a 24 hour service.

The review team concluded in the interim report that arrangements for the provision of neonatal care would be greatly strengthened by the establishment of a formal managed neonatal network. The network should ensure that the neonatal resources across the region are utilised to best effect and that units are working to common policies and procedures.

During the second phase of the review the review team was advised by all organisations that they supported this recommendation. Action is taking place to establish a formal managed neonatal network and to review the hours of operation of the Neonatal Transfer Service.

9.5.2 Reference to impact on staff

The review team met many clinical and managerial staff during the course of this review. The review team found that staff had been deeply affected by the consequences of the outbreaks of pseudomonas and there was a universal desire to identify measures which could be put in place, designed to prevent them happening again.

The review team concluded that organisations did have sufficient arrangements in place to provide support and has recommended that these are reviewed following these incidents. Such arrangements should be part of incident planning.

9.6 To consider the experience of families of babies affected by the pseudomonas infection and colonisation within neonatal units since 1 November 2011

Members of the review team met with families of babies who has been infected or colonised with pseudomonas during these incidents. The families stated that their decision to share their experience with the review team was influenced by their understanding that lessons would be learned, and recommendations made to try to prevent such outbreaks happening again.

The impact on families affected was profound. Through the experiences shared by the families, the review team concluded that there is important learning on how families are communicated with at such a difficult time for them.

In general, families were satisfied with the standard of care provided for their babies but felt that communication, in particular the level of language and information regarding the seriousness of the pseudomonas colonisation/infection, could in some cases have been improved.

Families felt that there was a need to use plain language when giving information to them about their baby and the situation in the neonatal unit. Where possible, information should be passed on in an appropriate, private setting. Parents should also be given the opportunity to have support, either from other family members or through external support organisations.

In some instances clinicians were concentrating their efforts on babies who were very sick, but as a consequence of this parents of babies who had been colonised felt that their concerns were not being addressed.

Specific leaflets giving information for parents whose babies had been colonised and a separate leaflet for those with babies who had been infected with pseudomonas would have helped. However, leaflets should not replace personal contact.

Parents need consistent information in a timely manner. Parents must be informed before information appears in the media. Medical and nursing staff should have daily meetings to agree the content of such information. This should also be communicated to staff at the beginning of each shift. In small units it is easier to have one-to-one contact with parents, however in larger units this becomes more difficult.

General meetings involving a number of parents allow information to be passed on to larger numbers. However, the parents told the review team that doctors did not feel they could explain what was going on in the unit due to confidentiality. The parents felt this was unsatisfactory.

Clinical staff should be provided with sufficient support to allow them to concentrate on clinical matters, with other roles taken on by non-clinical staff. This could all be set out in a communications plan, developed with the assistance of a trust communications department.

The review team considers that the identification of a specific term of reference for this review, to examine the experience of families made a significant difference to how the review was carried out and would commend this approach for future reviews.

Professor Troop and the members of the review team sincerely thank all family members who came forward and shared their experiences.

9.7 To identify any learning and make recommendations for all organisations involved

In the interim report, the review team made 15 recommendations for actions to enhance the safety and provision of services. These are set out in Appendix A.

The review team has made a further 17 recommendations following Phase Two of the review which are set out in Section 10.

10. Summary of Recommendations from Phase Two

- 1. All trusts should develop a communications plan for incidents including arrangements for engaging with families. The plans should ensure that clinical staff are provided with sufficient support to allow them to concentrate on clinical matters, with other roles taken on by non-clinical staff.
- Trusts should establish arrangements for independent validation of their selfassessment processes for water management compliance with statutory requirements and guidance.
- 3. Trusts should maintain an evidence file of compliance with L8 and HTM 04-01.
- 4. Trusts should maintain up to date registers of all those with named responsibilities under Approved Code of Practice L8 and that each is provided with written authorisation to carry out their statutory functions in water management.
- 5. Trusts should ensure that their written schemes for water management are kept up to date to reflect changes in procedures and facilities.
- 6. Trust should review the training needs of staff with prescribed functions in water management and ensure appropriate accredited training is provided when required.
- 7. Trusts should develop Water Safety Plans for Legionella, Pseudomonads and other opportunistic water pathogens as recommended in Annex A (2) of the DHSSPS Circular HSS (MD) 16/2012 issued on 30 April 2012.
- 8. Trusts should develop an annual action plan for water management which should be submitted to Trust Board for approval.
- 9. Trusts should review their governance arrangements for infection prevention and control in accordance with the NICE Quality Improvement Guide: "Prevention and Control of Healthcare Associated Infections".
- 10. The Public Health Agency should establish a weekly health protection alert bulletin for health protection professionals across Northern Ireland.
- 11. All HSC organisations should review their systems to ensure that any unusual incidents or intelligence related to infectious diseases are promptly shared with the PHA duty room.
- 12. All organisations should review their arrangements for sharing and documenting information received in relation to infectious disease incidents.
- 13. A joint plan across relevant organisations for the regional response to the management of outbreaks, affecting more than one organisation, should be developed, which clearly identifies the roles of each organisation.

- 14. The review team recommends that trusts should ensure that high impact interventions related to key clinical procedures are implemented and assured using a standardised common approach across all neonatal units
- 15. Guidelines should be developed for the organisation of, and participation in, regional teleconferences for future incidents.
- 16. All organisations should review their arrangements for supporting staff during incidents including outbreaks and ensure that incident plans include provision for support for staff both during and after incidents.
- 17. The recommendation on using sterile water in the interim report should be kept under review in relation to babies in Level III neonatal units (Special Care Baby Units) as new evidence emerges.

11. Glossary of Terms and Abbreviations

ARHAI Antimicrobial Resistance and Healthcare Associated Infection

Belfast Trust Belfast Health and Social Care Trust

CAH Craigavon Area Hospital

DH Department of Health (England)

DHSSPS Department of Health and Social Services and Public Safety

HP Health Protection

HPA Health Protection Agency

HSCB Health and Social Care Board

IPC Infection Prevention Control

NIC Neonatal Intensive Care

NICU Neonatal Intensive Care Unit

NNU Neonatal Unit

Northern Trust Northern Health and Social Care Trust

PCSS Patient Client Support Services

PHA Public Health Agency

RQIA Regulation and Quality Improvement Authority

RBHSC Royal Belfast Hospital for Sick Children

RJMS Royal Jubilee Maternity Service

SCBU Special Care Baby Unit

South Eastern Trust South Eastern Health and Social Care Trust

Southern Trust Southern Health and Social Care Trust

Western Trust Western Health and Social Care Trust

Appendix A

Recommendations of Interim Report published on 4 April 2012

- The current interim guidance that sterile water should be used when washing all babies in neonatal care (Levels 1, 2 and 3) should be continued pending early consideration of the Department of Health (England) guidance issued on 30 March 2012.
- 2 Tap water should not be used in maternity and neonatal units during the process of defrosting frozen breast milk.
- The current arrangements for testing water in neonatal units in Northern Ireland for pseudomonas should be continued pending early consideration of the Department of Health (England) guidance issued on 30 March 2012. This guidance sets out recommendations for water testing for all augmented care units including neonatal care.
- The presentation of test results of water samples should be standardised across the laboratories which undertake this for HSC organisations.
- The review team recommends that guidance on cleaning sinks should be reviewed so that practice is standardised across all clinical areas.
- Regional guidance on the cleaning of incubators and other specialist equipment for neonatal care should be produced.
- 7 Independent validation of hand hygiene audits should be carried out on a regular basis, supported by robust action plans where issues of non-compliance are identified.
- The intensive care accommodation in the neonatal unit at Antrim Area Hospital should be expanded to allow more circulation space around cots.
- 9 Pseudomonas aeruginosa should be identified as an alert organism for neonatal intensive and high dependency care. When identified from a sample from a baby, taps and sinks should be tested in rooms which had been occupied by that baby since birth.
- Surveillance arrangements should be established for *Pseudomonas aeruginosa* for augmented care settings including neonatal care.
- All relevant organisations should work to an agreed regional protocol for the declaration of outbreaks.
- Arrangements for the typing of strains of *Pseudomonas aeruginosa* should be established in Northern Ireland.

- A regional neonatal network should be formally established in Northern Ireland.
- The hours of availability for the regional transfer service for neonates should be expanded with plans put in place to move to a 24 hour service.
- The development of the new Regional Neonatal Intensive Care Unit at Royal Jubilee Maternity Service should be expedited as soon as possible. In the interim period, improved accommodation for the purposes of isolation and for the cleaning of equipment should be made available for the current unit. Steps to improve the space around each cot should be considered.

Appendix B

Circular HSS(MD)15/2012 issued on 6 April 2012

From the Chief Medical Officer Dr Michael McBride

HSS(MD)15/2012



For Action:

Chief Executives of HSC Trusts (for onward distribution to Directors of Infection and Prevention Control, Estates and Facilities Managers and those with responsibility for the safe operation of the water distribution systems within the Trust)

Chief Executive, Health and Social Care Board

Chief Executive, Public Health Agency

Chief Executive, NIAS

Chief Executive, RQIA

Medical Directors of HSC Trusts (for onward distribution to relevant medical staff)

Executive Medical Director/Director of Public Health, PHA (for onward distribution to all relevant public health staff)

Directors of Nursing, HSC Trusts (for onward distribution to relevant nursing staff)

Chairpersons of HSS Trusts

Castle Buildings Stormont BELFAST BT4 3SQ

Tel: 028 9052 0563 Fax: 028 9052 0574

Email: michael.mcbride@dhsspsni.gov.uk

Your Ref:

Our Ref: HSS(MD)15/2012 Date: 6 April 2012

Dear Colleague

PSEUDOMONAS UPDATE:

1. INTERIM REPORT OF THE INDEPENDENT REVIEW OF INCIDENTS OF PSEUDOMONAS AERUGINOSA INFECTION IN NEONATAL UNITS IN NORTHERN IRELAND; AND

2. WATER SOURCES AND POTENTIAL PSEUDOMONAS AERUGINOSA CONTAMINATION OF TAPS AND WATER SYSTEMS – ADVICE FOR AUGMENTED CARE UNITS

Introduction

- The purpose of this letter is to advise you of the publication of two reports on pseudomonas:
 - The Interim Report of the Independent Review of Incidents of Pseudomonas aeruginosa Infection in Neonatal Units in Northern Ireland
 and
 - Water sources and potential Pseudomonas aeruginosa contamination of taps and water systems – advice for augmented care units.



Background in Northern Ireland

- Following the incident of Pseudomonas infection in Altnagelvin neonatal unit, we wrote to Trusts on 22 December 2011 to remind them of the potential infection risks posed by water systems in healthcare facilities and to reinforce important messages contained in two earlier communications issued in September 2010 and July 2011.
- 3. In the following weeks, further specific advice was required to address the emerging microbiological evidence of *Pseudomonas* associated with taps in neonatal units. Because there was no UK guidance available to inform the appropriate actions, interim guidance had to be developed in conjunction with experts from the Health Protection Agency and the Public Health Agency. This was communicated in our letter HSS(MD) 4/2012 *Interim guidance on Pseudomonas and neonatal units* which was issued on 28 January. That letter concluded with the comment that 'at this stage, national guidance on *Pseudomonas* is nearing completion and we anticipate that this will be issued in the near future. In the meantime, given the need for clear direction and advice in Northern Ireland, this interim advice has been developed in full consultation with the Health Protection Agency. This is an evolving situation and further advice will be issued as required.'
- 4. Further advice was then required to address two specific issues: (i) the schedule for Pseudomonas aeruginosa testing of water following installation of new taps in neonatal units; and (ii) updated advice for other augmented care units. This interim advice was issued in our letter of 9 February, HSS(MD) 6/2012: Water sources and potential for Pseudomonas aeruginosa infection from taps and water systems: Further interim Northern Ireland guidance.
- 5. The 9 February letter stated: 'This interim guidance has been developed in consultation with the Health Protection Agency and Public Health Agency. It is situation-specific and applies only to Northern Ireland in the current context of *Pseudomonas* infections and colonisations in babies in neonatal units and subsequent detection of *Pseudomonas* in water samples from taps producing water which may have direct or indirect patient contact. The interim guidance should not be generalised to other UK countries or outbreaks. It is a pragmatic response to an identified need, pending publication of national guidance. While learning from the situation in Northern Ireland will inform the national guidance, the recommendations in this and earlier letters should not be taken as an indication of the form of national guidance currently in preparation'.
- 6. Included in that letter as an Annex was the Best Practice advice which had been issued by the Department of Health in England on 6 February 2012. This referred specifically to (i) Best Practice for hand wash stations to minimise the risk of Pseudomonas aeruginosa contamination; and (ii) Best Practice for assessing and managing the risks in augmented care units to minimise the risk of Pseudomonas aeruginosa contamination. The letter stressed that while the Best Practice advice was applicable to all settings, it



was important to note that during management of the current situation in Northern Ireland, additional interim guidance applied to neonatal units. Where there was any conflict between the Northern Ireland interim guidance for neonatal units and the best practice notes, the NI interim guidance took precedence at that time.

The Interim Report of the Independent Review of Incidents of Pseudomonas aeruginosa Infection in Neonatal Units in Northern Ireland

- 7. On 31 January the Minister made a statement to the Assembly to update Members on the pseudomonas incidents in neonatal units. He said then that he had asked the Regulation and Quality Improvement Authority (RQIA) to facilitate an independent review of these incidents, and had asked for an interim report by end of March so that urgent actions could be taken.
- The Interim Report of the Independent Review of Incidents of Pseudomonas
 aeruginosa Infection in Neonatal Units in Northern Ireland was published on 4
 April on the RQIA's website:
 http://www.rqia.org.uk/cms_resources/RQIA%20Independent%20Review%20
 of%20Pseudomonas%20Interim%20Report.pdf.
- The Interim Report focuses on the first two Terms of Reference of the review.
 These were: (1) to investigate the circumstances contributing to the occurrences of pseudomonas infection in neonatal units from 1 November 2011, and (2) to review the effectiveness of the Trusts' management of the occurrences of pseudomonas infection and colonisation within neonatal units.
- The Review Team has made 15 recommendations which are attached in Annex A. A number of these can be implemented immediately.

Water sources and potential Pseudomonas aeruginosa contamination of taps and water systems – advice for augmented care units

- New best practice technical guidance entitled Water sources and potential Pseudomonas aeruginosa contamination of taps and water systems – advice for augmented care units was published on the Department of Health (DH) website on 30 March 2012. This is available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_133317 and provides advice for health care providers across the UK on:
 - assessing the risk to patients if water systems become contaminated with P. aeruginosa or other opportunistic pathogens;
 - (ii) what actions to take if water systems become contaminated with P. aeruginosa;
 - (iii) protocols for sampling, testing and monitoring water for P. aeruginosa: and



- (iv) developing local water safety plans
- 12. This guidance has been developed by the Department of Health (London), working with national experts in this subject area. Learning from the recent experiences of Pseudomonas in neonatal units in Northern Ireland has contributed to the development of the best practice technical guidance. The Department is preparing and, by the end of April, will issue updated Northern Ireland guidance which will be based on the DH technical guidance and take into account the RQIA interim Recommendations.

FOR ACTION: Implementation of the RQIA Interim Recommendations

- In the interim, pending issue of updated DHSSPS guidance:
 - Neonatal units and other augmented care units should continue to adhere to the current Northern Ireland interim guidance; and
 - Trusts should take forward the recommendations as outlined in Annex A.
- The Minister has asked the Chief Medical Officer to oversee the speedy implementation of all the recommendations and to seek assurance from HSC organisations about implementation. Dr Andrew McCormick will write separately to the Chief Executives of HSC Trusts, HSCB and PHA.

Yours sincerely

Dr Michael McBride Chief Medical Officer

Audra & Sugar Da

Mr John Cole Deputy Secretary/Chief Estates Officer

This letter is available on the DHSSPS website at

www.dhsspsni.gov.uk/index/phealth/professional/cmo_communications.htm



Annex A

PSEUDOMONAS REVIEW INTERIM REPORT RECOMMENDATIONS

	Recommendation	Implementation
1	The current interim guidance that sterile water should be used when washing all babies in neonatal care (Levels 1,2 and 3) should be continued pending early consideration of the Department of Health (England) guidance issued on 30 March 2012.	(i) All Trusts will continue to follow the current interim NI guidance, HSS(MD)4/2012, on using sterile water when washing all babies in neonatal units and assure themselves the guidance is being adhered to. (ii) The Department will develop and issue updated Northern Ireland guidance by end April 2012.
2	Tap water should not be used in maternity and neonatal units during the process of defrosting frozen breast milk.	All Trusts will implement this recommendation immediately.
co.	The current arrangements for testing water in neonatal units in Northern Ireland for pseudomonas should be continued pending early consideration of the Department of Health (England) guidance issued on 30 March 2012. This guidance sets out recommendations for water testing for all augmented care units including neonatal care.	(i) All Trusts will continue to follow current interim NI guidance, HSS(MD)4/2012 and HSS(MD)6/2012, for testing water in neonatal units for pseudomonas. (ii) The Department will develop and issue updated Northern Ireland guidance by end April 2012.
4	The presentation of test results of water samples should be standardised across the laboratories which undertake this for HSC organisations.	The Microbiology Network will develop an agreed regional standardised presentation of test results of water samples by end May 2012.
5	The review team recommends that guidance on cleaning sinks should be reviewed so that practice is standardised across all clinical areas.	The Department will review and issue regional guidance on cleaning sinks by end May 2012.
6	Regional guidance on the cleaning of incubators and other specialist equipment for neonatal care should be produced.	The Department will develop and issue regional guidance by end April 2012.
7	Independent validation of hand hygiene audits should be carried out on a regular basis, supported by robust action plans where issues of non-compliance are identified.	All Trusts will implement this immediately.
8	The intensive care accommodation in the neonatal unit at Antrim Area Hospital should be expanded to allow more circulation space around cots.	The Northern Trust is currently considering a number of options for improving accommodation at the neonatal unit at Antrim Areas Hospital in line with the report



		recommendations and will agree the
		project implementation plan with the
		Department by end of May 2012.
9	Pseudomonas aeruginosa should be	(i) All Trusts will implement this
-	identified as an alert organism for	immediately.
	neonatal intensive and high dependency	(ii) PHA will work with all Trusts and
	care. When identified from a sample from	the Neonatal Network to develop
	a baby, taps and sinks should be tested	systems and protocols for sharing
	in rooms which had been occupied by	appropriate information about P.
	that baby since birth.	aeruginosa infections and
		colonisations between Neonatal Units by end May 2012.
10	Surveillance arrangements should be	PHA, working with the Department
	established for Pseudomonas aeruginosa	and all Trusts, to lead development
	for augmented care settings including	of enhanced surveillance for P.
	neonatal care.	aeruginosa by end October 2012.
11	All relevant organisations should work to	PHA to develop and issue an
	an agreed regional protocol for the	agreed regional protocol for
	declaration of outbreaks.	implementation in all Trusts by end
		May 2012.
12	Arrangements for the typing of strains of	HSCB with advice from PHA, all
	Pseudomonas aeruginosa should be	Trusts and Microbiology Network,
	established in Northern Ireland.	will commission arrangements to
		type P. aeruginosa – to be in place
4.00		by end of December 2012.
13	A regional neonatal network should be	HSCB with advice from PHA, all
	formally established in Northern Ireland.	Trusts and Neonatal Network, will
		agree arrangements to formally
		establish the neonatal network as a
		managed clinical network by
		September 2012.
14	The hours of availability for the regional	Current provision is 60 hours of
	transfer service for neonates should be	cover perweek. HSCB to consider
	expanded with plans put in place to move	potential for further expansion of this
	to a 24 hour service.	service by end July 2012.
15	The development of the new Regional	Department to work with HSCB/PHA
	Neonatal Intensive Care Unit at Royal	Neonatal Service commissioners
	Jubilee Maternity Service should be	and Belfast Trust to explore options
	expedited as soon as possible. In the interim period, improved accommodation	for improving accommodation in line with the recommendations at the
	for the purposes of isolation and for the	neonatal intensive care unit at
	cleaning of equipment should be made	RJMH, ahead of planned completion
	available for the current unit. Steps to	of new RVH maternity unit in
	improve the space around each cot should be considered.	December 2015 – agree plan by end May 2012.
<u> </u>	snould be considered.	OHU MAY ZUIZ.



