The Regulation and Quality Improvement Authority

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

Interim Report

31 March 2012

informing and improving health and social care
www.rqia.org.uk

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.

Foreword by Professor Pat Troop

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

On 30 January 2012, Edwin Poots, MLA, Minister for Health, Social Services and Public Safety, asked RQIA to undertake a review into the incidents of pseudomonas in neonatal care settings in Northern Ireland, with an interim report to be produced by the end of March 2012.

The review team was established comprising leading experts in the fields of neonatology, microbiology, and medical engineering from across the United Kingdom. I am particularly grateful for the contribution of the representatives of Bliss and Sands, two national voluntary organisations with specific expertise in this area.

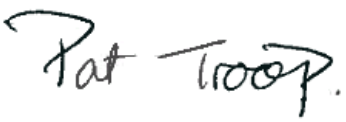
This interim report presents our findings relating to the first two terms of reference: to examine the cause of the infection; and to consider the responses of the organisations involved.

We met with the families of a number of the infants colonised and infected with pseudomonas, including some of those who tragically lost a baby. I sincerely thank these families for their openness, honesty and their willingness to contribute at such a difficult time. We will continue our engagement with families during the second phase of this review and we extend an invitation to any other families who have been affected, if they wish to meet with the review team.

I am very grateful for the co-operation of staff in all of the health and social care organisations under review: the five health and social care trusts; the Health and Social Care Board; the Public Health Agency; and the Department of Health, Social Services and Public Safety.

We have found that everyone we have spoken to has been deeply affected by the tragic loss of life. Staff have asked us to make sure that all possible steps are taken to protect infants from harm.

This interim report makes 15 recommendations for immediate consideration by the Minister. The final report of the review will be presented to the Minister in late May 2012 and will include a particular emphasis on the experiences of the families.



Professor Pat Troop CBE FRCP FFPH DSc
Review Chair

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Foreword by Professor Pat Troop

1. Introduction and Background to 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 neonatal unit in the Royal Jubilee Maternity Service (RJMS), Belfast, for surgery for an unrelated condition.

On 17 January 2012 the Belfast Health and Social Care Trust (Belfast Trust) declared an outbreak of *Pseudomonas aeruginosa* infection in the neonatal unit of the Royal Jubilee Maternity Service. 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 in December. A third baby also died after the outbreak was declared.

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 the Minister for Health, Social Services and Public Safety, Mr Edwin Poots, 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. An interim report was requested by the Minister by 31 March 2012 to ensure that lessons learned were acted on as soon as possible. A final report is to be submitted to the Minister by 31 May 2012. Terms of reference were agreed and RQIA established the review team under the chairmanship of Professor Pat Troop.

The death of their newborn babies was devastating for families. The period of the outbreaks was also extremely stressful for those families whose babies were either infected or colonised with pseudomonas. The terms of reference outlined that the review team would engage directly with the parents of babies who had been affected by the outbreak. The review team considered that it was important to meet with families at an early stage to find out if they had questions that they felt could be answered through the review. They also wished to allow them to share information in order to inform the review findings. The interim report outlines some themes that were identified during discussions with those parents who the review team has already met. These will be considered in detail in the final report.

During this phase of the review, team members spoke with staff from organisations across Northern Ireland. The review team was impressed with the professionalism of all staff and it was evident that the incidents in the neonatal units had a significant impact on them. Staff expressed their commitment to following any recommendations that would improve the neonatal service in Northern Ireland.

The interim report provides a high level timeline of events. It sets out the interim findings of the review team as to the circumstances leading to the pseudomonas incidents and how they were responded to.

It provides an initial set of recommendations for consideration by the Minister based on the findings and conclusions of this stage of the review.

We would like to thank all parents who shared their experiences with us at this very difficult time. We are also grateful to the staff in all organisations who facilitated the review team during this phase of the 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 and 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 would cover the period 1 November 2011 to 31 January 2012.

The review would be 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 will be 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 requested two reports:

An interim report completed by the end of March 2012 which would highlight the key findings and provide recommendations arising from phase one which should be implemented immediately to assure the safety of the neonatal service; and

A final report completed by the end of May 2012 which would provide more detail and further recommendations for the service and include findings from phase two.

This report comprises the interim report, which was submitted to the Minister on 30 March 2012.

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 as well as former Deputy Chief Medical Officer at the Department of Health (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, RQIA Director of Reviews and Medical Director, Belfast

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 entitled 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:

1. 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 (NICUs) 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

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, to include:

- DHSSPS staff
- PHA staff
- HSC Board staff
- Chief Executives
- Medical Directors
- Trust estates personnel
- Trust facilities personnel
- Trust infection control personnel
- Trust medical staff
- Trust nursing staff
- Trust microbiologists
- Belfast Trust Root Cause Analysis Investigation Team

Various meetings were also held with parents and grandparents of eight families who have been affected directly by the *Pseudomonas aeruginosa* infection. Families whose babies had been affected by the outbreaks were invited to meet with the review team. Phase two of the review will continue to provide opportunities for other families to come forward to share their experience with the review team.

During phase one, liaison with national organisations, including the Health Protection Agency, has also taken place to ensure a comprehensive understanding of what is happening across the United Kingdom.

4. Background and Context to the Provision of Neonatal Care in Northern Ireland

4.1 Health and Social Care in Northern Ireland

Health and social care in Northern Ireland is provided as an integrated service. There are a number of organisations who work together to plan, deliver and monitor health and social care across Northern Ireland.

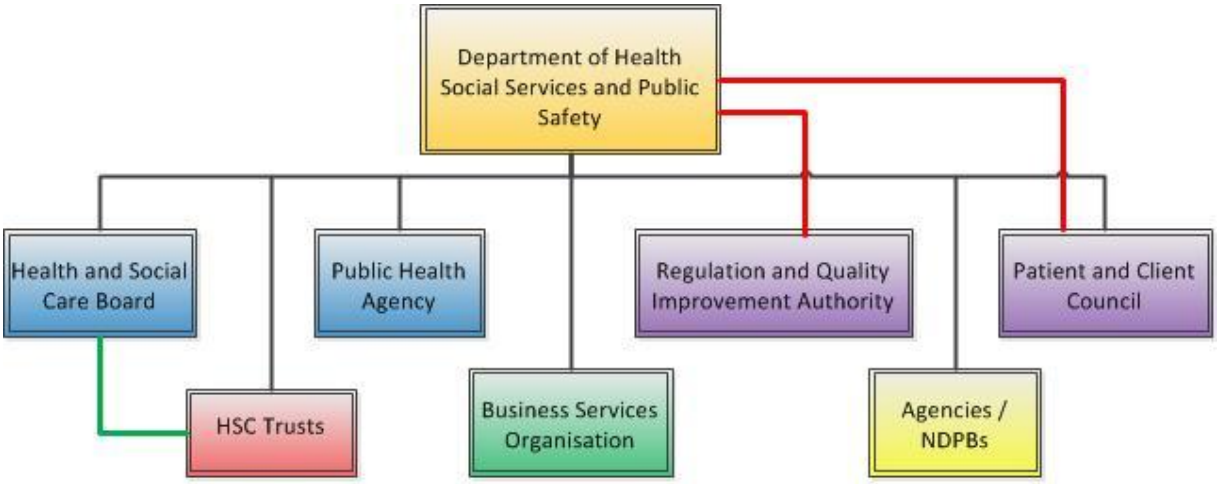

Figure 4(a): Health and Social Care Structure in Northern Ireland

Department of Health, Social Services and Public Safety (DHSSPS)
The DHSSPS has three main business responsibilities:

- **Health and Social Care (HSC)**, which includes policy and legislation for hospitals, family practitioner services and community health and personal social services
- **Public Health**, which covers policy, legislation and administrative action to promote and protect the health and well-being of the population
- **Public Safety,** which covers policy and legislation for fire and rescue services.

Within the DHSSPS, the key business groups are the Resource and Performance Management Group, the Healthcare Policy Group, the Social Policy Group, the Health Estates Investment Group (HEIG), the Chief Medical Officer Group (encompassing the Population Health Directorate) and the Office of Social Services. The DHSSPS also has a Modernisation Directorate and a Human Resources Directorate.

Health and Social Care Board (HSCB)
The HSCB is responsible for commissioning services, resource management and performance management and service improvement. It works to identify and meet the needs of the Northern Ireland population through its five local commissioning groups which cover the same geographical areas as the HSC trusts.

Public Health Agency (PHA)
The PHA has the key functions of improving health and wellbeing and health protection. It also provides professional input to the commissioning process. The PHA is jointly responsible (with the HSCB) for the development of a fully integrated commissioning plan for health and social care in Northern Ireland. The organisation works in partnership with local government, key organisations and other sectors to improve health and wellbeing and reduce health inequalities.

Health and Social Care Trusts
There are a total of six health and social care (HSC) trusts in Northern Ireland. Five HSC trusts provide integrated health and social care services across Northern Ireland:

- Belfast HSC Trust (Belfast Trust)
- Northern HSC Trust (Northern Trust)
- South Eastern HSC Trust (South Eastern Trust)
- Southern HSC Trust (Southern Trust)
- Western HSC Trust, (Western Trust)

The HSC trusts manage and administer hospitals, health centres, residential homes, day centres and other health and social care facilities and they provide a wide range of health and social care services to the community.

The sixth trust is the Northern Ireland Ambulance Service Trust (NIAS), which operates a single Northern Ireland-wide service and aims to improve the health and well-being of the community through the delivery of high quality ambulance services.

The DHSSPS, HSCB, PHA and the HSC trusts are the organisations which are subject to this review.

4.2 Admissions of Babies to Neonatal Care

In 2010 there were 25,300 live births registered in Northern Ireland, a small increase (2%) on the number of births registered in 2009.[1] Each year approximately 2,000 newborn babies in Northern Ireland will need extra care and will be admitted to a neonatal unit. Most of these will need intensive or high dependency care.[2]

Babies who are most likely to require admission to a neonatal unit are:

- premature babies (a baby who is born before a gestational age of 37 completed weeks is considered to be premature)
- low birth weight babies (a baby that weighs less than 2,500 grams at birth is considered to be of low birth weight)
- babies with congenital abnormalities or other medical problems
- babies requiring assessment and/or management for acquired surgical problems
- babies born to mothers who have had problems during pregnancy
- multiple births

[1] Births in Northern Ireland 2010: Northern Ireland Statistics and Research Agency (NISRA) - http://www.nisra.gov.uk/archive/demography/publications/births_deaths/births_2010.pdf
[2] Neonatal Intensive Care Outcomes Research and Evaluation (NICORE) - http://www.publichealth.hscni.net/directorate-public-health/service-development-and-screening/nicore

Neonatal units in hospitals specialise in the care of those babies born early with low weight or who have a medical condition that requires specialised treatment.

One in nine babies born in the United Kingdom will spend at least a few days in a neonatal unit. Some babies may need breathing support or monitoring, some may have an infection and need antibiotics, and some may be suffering from other medical conditions. The length of a baby's stay may vary from days, to weeks or months, depending on their needs.

A premature baby can face many problems such as hypothermia, respiratory conditions and jaundice and they will be susceptible to infections.

In the unit, a baby may be attached to monitors and may have intravenous lines inserted. It may not be possible to hold the baby, or it may not be possible to do so for long.

High staff / patient ratios, specialised equipment and treatment make neonatal services a high cost, relatively low volume specialty. Daily, or even hourly fluctuations, in relatively small numbers of babies result in peaks and troughs of activity, which are much more marked than in higher volume services.

4.3 Provision of Neonatal Services in Northern Ireland

4.3.1 Levels of Care

There are three levels of care in Northern Ireland, namely:

Level 1: Neonatal Intensive Care (NIC)
This care is provided for babies with the most complex problems who require constant supervision and monitoring and, usually, mechanical ventilation. Due to the possibility of acute deterioration, a trained doctor must always be available. Extremely immature infants all require intensive care and monitoring over the first weeks.

Level 2: High Dependency Care (HDU)
This care takes place in a neonatal unit and involves care for babies who need continuous monitoring, for example those who weigh less than 1,000 grams, or are receiving help with their breathing via continuous positive airway pressure (CPAP) or intravenous feeding, but who do not fulfil any of the requirements for intensive care. A trained doctor should be available.

Level 3: Special Care
This care is provided for all other babies who could not reasonably be looked after at home by their mother. Babies receiving special care may need to have their breathing and heart rate monitored, be fed through a tube, supplied with extra oxygen or treated for jaundice. This category also includes babies who are recovering from more specialist treatment before they can be discharged. Special care which occurs alongside the mother is often called 'transitional care' but takes place outside a neonatal unit, in a ward setting.

4.3.2 Policy

In June 2005 the Chief Medical Officer commissioned a paper in response to concerns that the existing neonatal service in Northern Ireland was unable to meet rising demand. A small project group was established to provide a robust baseline position for specialist neonatal services activity in Northern Ireland, and to inform future service planning, provision and development. The resulting paper was published in May 2006.[3]

The conclusions of the paper included:

- regarding nursing staff, Northern Ireland has a skilled and committed neonatal workforce but capacity to train an increased number of neonatal nurses was a priority to meet future service requirements;
- regarding medical staff, out of hours consultant medical cover for area neonatal units includes neonatologists, acute paediatricians and community paediatricians. This was concerning if very premature or extremely low birthweight babies were unable to access the regional unit for their initial care. Future cot configuration should take into account 24 hour medical staffing;
- babies born before 28 weeks gestation and weighing less than 1,000 grams should receive their initial care in the regional unit with 24 hour neonatal cover;
- once care in the regional unit is no longer required, transfer or repatriation of these babies should be considered to free up cots for other newborns requiring regional care;
- very low birthweight babies, (<1500gms) comprise around 1% of total births, account for almost a quarter (24%) of admissions and over half (54%) of total level 1 and 2 days. The impact of a few additional babies in this category would therefore have a disproportionately large effect on number of cot days, particularly in the regional unit;
- highest occupancy levels were in level 2 cots;
- a regional transfer system was considered to be essential for units to fully function as a network;
- an effective managed clinical network for neonatal services would require full commitment from obstetricians, paediatricians and trust management; and
- patients and the public would require information and education about the purpose and functions of a managed clinical network and the implications this may have for the location of their care.

[3] Position Paper on Specialist Neonatal Services in Northern Ireland (May 2006): http://www.dhsspsni.gov.uk/neonatalservicesinni.pdf

4.3.3 Neonatal Care Settings in Northern Ireland

Whilst there is an informal neonatal network in Northern Ireland, units are independent and autonomous. Neonatal services are provided by:

One regional unit
The Royal Jubilee Combined Neonatal Intensive Care and Special Care Baby Unit based at the Royal Jubilee Maternity Hospital in Belfast (Belfast Trust).

Four area Neonatal Units which provide neonatal intensive care, high dependency care and special care. They are:

1. Antrim Area Hospital in Antrim (Northern Trust)
2. The Ulster Hospital in Belfast (South Eastern Trust)
3. Craigavon Area Hospital in Craigavon (Southern Trust)
4. Altnagelvin Hospital in Londonderry (Western Trust)

There are also **two Neonatal Units providing special care (Level 3) (SCBUs)** at:

1. Daisy Hill Hospital in Newry (Southern Trust)
2. Erne Hospital in Enniskillen (Western Trust)

Causeway Hospital in Coleraine (Northern Trust) has paediatric services on site and can stabilise babies prior to transfer to another unit.

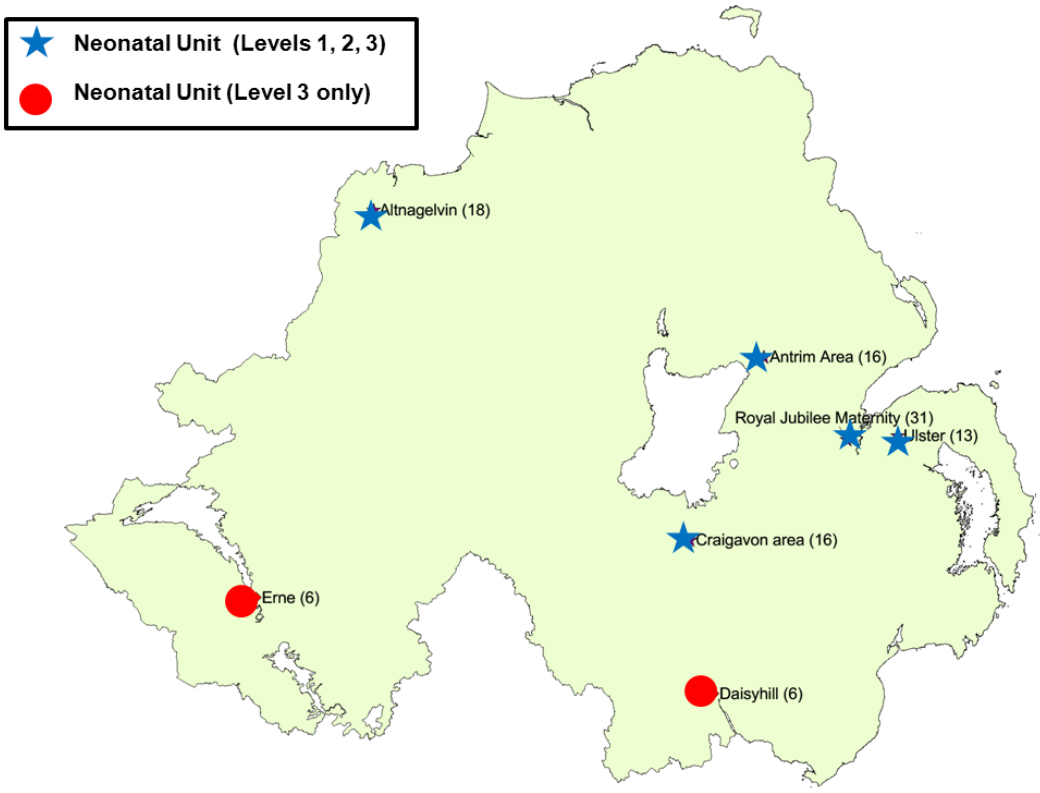

Figure 4(b): Map of Neonatal Units in Northern Ireland (Number of Cots in Brackets)

Belfast Trust: The Regional Unit (Royal Jubilee Maternity Service (RJMS))
This is a combined neonatal and special care baby unit. It is based in the Royal Jubilee Maternity Hospital and is located on the Royal Group of Hospitals site in Belfast. It was constructed in 1934, with two major extensions added (circa 1960/1970) and provides the entire range of pre and post-natal maternity services. The neonatal unit incorporating NICU is located within the main block.

The NICU was opened in December 1993 with a large intensive care room (ICU) and three rooms with four cots. This unit is funded for 9 level 1 cots, 7 level 2 and 15 level 3.
In February 2000, the Royal Jubilee NICU amalgamated with Royal Maternity neonatal unit, and cots increased to 31 with an additional two rooms in the new special care area, Rooms 1 and 2. In 2006, due to an infection, the unit was repainted, vaporised and clinical units built beside each incubator space in ICU.

Some refurbishment has taken place since August 2011:

- 19 August – 12 September 2011 the floor in ICU was replaced, central units were replaced, and wash hand basins with sensor taps were installed.
- 20 September - 4 October 2011: the floors in the main corridor and rooms 5a, 5b and 5c were replaced, as well as wash hand basins and sensor taps installed.
- 20 January 2012 – 6 February 2012 the ICU was again refurbished, with central panel's new sinks and sensor taps with ultra violet (UV) point of use (POU) devices.
- 8 February 2012 – present: rooms 5a, 5b and 5c are having new panels, new sinks and sensor taps with UV POU devices installed.

Northern Trust: Antrim Hospital Neonatal Unit
Antrim Area Hospital which included a Neonatal Unit was opened in 1994.

The unit consists of 16 cots, six of which are intensive care cots, two sets of four nursery cots and two single isolation cots.

South Eastern Trust: Ulster Hospital Neonatal Unit
This NICU opened in 2007 as part of the new maternity building. It consists of two clinical areas:

- ICU/HDU area with five cots, and
- SCBU area with 10 cots

In addition, there is a side room where a baby may be stabilised prior to transfer to another unit when no other space is available or for a baby requiring palliative care.

The trust is currently only funded to have 13 cots (two Level 1, two Level 2, and nine Level 3). However, the physical space allows for 15 cots and this provides the flexibility to respond to regional demands. This has staffing and equipment resource consequences.

There are two ensuite parent bedrooms, a kitchenette, administrative space, two store rooms, two utility rooms, a test room, a staff toilet and staff room. There have been no extensions or refurbishments since the unit opened.

Southern Trust: Craigavon Hospital Neonatal Unit
This unit opened in 1972, with facilities for 28 special care cots.

Following a refurbishment programme in the early 1980s the piped air and oxygen supply to the unit was upgraded to facilitate an increasing number of admitted neonates who required more intensive respiratory support. Over the next decade there was a gradual reduction in the number of cots as instrumental deliveries and all caesarean section infants were no longer routinely admitted to the neonatal unit.

In 1987, the unit was formally upgraded to an intensive care unit with the introduction of an infant ventilator. In 2005 cot capacity was 14 (two intensive care level 1, four high dependency level 2 and eight special care level 3 cots). In 2006, in response to an increasing number of infants requiring intensive care, the intensive care nursery was refurbished and an additional level 1 intensive care cot was provided. Cot capacity was now 15 (three intensive care level 1, four high dependency level 2 and eight special care level 3 cots).

A further review of service took place in 2009 driven by increased demand from the southern area population and an increased birth rate at the hospital, creating pressures on maternity services. Alongside this came the introduction of a new service model for neonatology which would provide measures to alleviate pressures on cots in relation to level 3 care. An additional level 3 cot was introduced and plans put in place to provide two additional transitional care cots. The additional level 3 cot was opened in March 2011. Cot capacity increased to 16 (three level 1 intensive care cots, four high dependency level 2 cots and nine special care level 3 cots.) Health care assistants are currently completing a training programme to gain QCF level 3 accreditation and, on completion, transitional care cots on both the Craigavon and Daisy Hill sites will open.

In 2011, the reorganisation of facilities within the unit resulted in the creation of a dedicated isolation facility which could accommodate a level 1, 2 or 3 infant. An existing nursery was also upgraded. The new service model for neonatology within the Southern Trust, supporting the introduction of the concept of transitional care, created two family rooms to allow infants who were within 24-48 hours of discharge to be nursed in these rooms with their parents under the supervision of neonatal staff.

Current capacity remains at 16 cots (three intensive care level 1, four high dependency level 2 and nine special care level 3 cots). When transitional care is introduced April 2012 onwards, cot capacity will be 18 (three intensive care, four high dependency and 11 special care cots, two of which will be utilised as transitional care cots).

Southern Trust: Daisy Hill Neonatal Unit providing Level 3 Care
This Neonatal Unit has been operational since the hospital was opened in 1981. The cot capacity is for six special care infants. The unit will admit and stabilise level 1 and level 2 infants prior to transfer.

The unit underwent a refurbishment in 2010, resulting in a change in the designation of one of the level 3 cots to be used flexibly as a level 2 cot approximately 25% of the time and provision of one additional transitional care cot. In addition, a separate isolation room was created along with enhanced facilities for parents.

Health care assistants are currently completing a training programme to gain QCF level 3 accreditation and, upon completion, the transitional care cot will open.

Western Trust: Altnagelvin Neonatal Unit
At present, the Neonatal Unit at Altnagelvin is an 18 cot unit. This unit has been in existence since the 1960's since the hospital was built.

The unit has been refurbished on several occasions during this time and moved to new premises in February 2009, where it is now situated in the south wing, Altnagelvin Hospital. There are 5 areas:

- ICU
- High dependency
- Special care
- Two single isolation rooms

Western Trust: Erne Neonatal Unit providing Level 3 Care
The Neonatal Unit at the Erne Hospital in Enniskillen was established in October 1994 and has always had a capacity of six cots.

This unit will be moving to South West Acute Hospital, Enniskillen, in June 2012.

4.4 Activity Levels

Numbers of Cots
There are 106 cots across Northern Ireland. Figure 4(c) outlines the number of cots by level in each Neonatal Unit across the five trust areas.

TRUST	BELFAST	NORTHERN	SOUTH EASTERN	SOUTHERN		WESTERN		NORTHERN IRELAND
UNIT	**Royal Jubilee**	**Antrim**	**Ulster**	**Craigavon**	**Daisy Hill**	**Altnagelvin**	**Erne**	**TOTAL**
Level 1	9	4	2	3	0	3	0	**21**
Level 2	7	2	2	4	0	6	0	**21**
Level 3	15	10	9	9	6	9	6	**64**
TOTAL	**31**	**16**	**13**	**16**	**6**	**18**	**6**	**106**

Figure 4(c): Number of Cots by Level across Northern Ireland. Source: Information provided by HSC Trusts (February 2012)

In Altnagelvin, 0.5 cots at Level 1 are funded by HSE, Republic of Ireland for transfers from Letterkenny General Hospital, County Donegal.

Numbers of Admissions

Figure 4(d) shows the numbers of admissions by level of cots across Northern Ireland between September 2010 and January 2012 inclusive.

TRUST	BELFAST	NORTHERN	SOUTH EASTERN	SOUTHERN		WESTERN		NORTHERN IRELAND	
UNIT	**Royal Jubilee**	**Antrim**	**Ulster**	**Craigavon**	**Daisy Hill**	**Altnagelvin**	**Erne**	**TOTAL**	**AVERAGE PER MONTH**
Level 1	422	191	139	250	28	137	39	1206	70.94
Level 2	242	74	215	59	10	129	12	741	43.59
Level 3	111	127	132	169	163	165	129	996	58.59
TOTAL	775	392	486	478	201	431	180	2943	**173.12**
AVERAGE PER MONTH	45.59	23.06	28.59	28.12	11.82	25.35	10.59	**173.12**	

Figure 4(d): Numbers of Admissions by Level of Cots across Northern Ireland between September 2010 and January 2012 inclusive. Source: Information provided by HSC Trusts (February 2012)

In Craigavon and Daisy Hill, admissions are based on new admissions (including transfers in from other sites) within the month and excludes babies already occupying a cot as at the last day of the previous month end. The level is based on the level on admission date.

Occupancy Rates

Figure 4(e) shows the occupancy rates (as a percentage) by level of cot across Northern Ireland between September 2010 and January 2012.

TRUST	BELFAST	NORTHERN	SOUTH EASTERN	SOUTHERN		WESTERN		NORTHERN IRELAND
UNIT	**Royal Jubilee**	**Antrim**	**Ulster**	**Craigavon**	**Daisy Hill**	**Altnagelvin**	**Erne**	**AVERAGE**
Level 1	78.86	47.18	39.24	61.24	0.00	62.06	0.00	**57.71**
Level 2	101.13	96.35	116.12	54.59	0.00	48.94	0.00	**83.43**
Level 3	68.72	101.74	93.53	89.65	63.06	72.88	60.35	**78.56**

Figure 4(e): Occupancy Percentage Rates by Level of Cots across Northern Ireland between September 2010 and January 2012 inclusive. Source: Information provided by HSC Trusts (February 2012)

In Erne the Unit cares for babies at Level 3. Babies at Levels 1 and 2 are stabilised and transferred out unless they only require that level for 28-48 hours.

Occupancy Rates

Figures 4(f), 4(g) and 4 (h) show the occupancy rates (as a percentage) for Levels 1, 2 and 3 cots across Northern Ireland between September 2010 and January 2012.

Units can use cots flexibly, particularly between Levels 1 and 2.

MONTH	LEVEL 1				
	Belfast Royal Jubilee	Northern Antrim	South Eastern Ulster	Southern Craigavon	Western Altnagelvin
Sep-10	70.00%	50.80%	35.00%	40.00%	45.00%
Oct-10	139.70%	54.00%	13.00%	52.00%	66.00%
Nov-10	81.40%	32.50%	30.00%	54.00%	31.00%
Dec-10	95.60%	58.00%	37.00%	57.00%	68.00%
Jan-11	96.70%	46.70%	11.00%	38.00%	49.00%
Feb-11	72.20%	28.60%	16.00%	44.00%	56.00%
Mar-11	61.20%	29.80%	18.00%	84.00%	65.00%
Apr-11	54.85%	54.00%	53.00%	49.00%	53.00%
May-11	66.60%	49.20%	45.00%	24.00%	32.00%
Jun-11	46.20%	23.30%	35.00%	50.00%	54.00%
Jul-11	67.30%	69.30%	37.00%	63.00%	34.00%
Aug-11	76.70%	27.40%	39.00%	92.00%	12.00%
Sep-11	65.90%	50.80%	55.00%	91.00%	81.00%
Oct-11	100.00%	79.80%	61.00%	29.00%	80.00%
Nov-11	82.20%	55.00%	37.00%	73.00%	127.00%
Dec-11	77.40%	31.50%	61.00%	73.00%	96.00%
Jan-12	86.70%	61.30%	84.00%	128.00%	106.00%

Figure 4(f): Occupancy Rates (%) by Level 1 Cot across Northern Ireland in 2011. Source: Information provided by HSC Trusts (February 2012)

	< 70%
	70%-94%
	> 94%

BELFAST TRUST: Notes. This information is an indicator and should be used indicatively only. When patients have not been discharged on the system i.e. a cot is apparently occupied by two patients at the one time. In specific regard to NICU there could also be issues in relation to the transfer between categories of levels of care i.e. there is quite a bit of transfer of babies between cots of differing levels of care which would exacerbate the issue.

SOUTHERN TRUST: CRAIGAVON Notes: % Occupancy Rate = Occupied Cots for each day in Month \ Available Cots by each day in Month. % Occupancy is a snapshot daily position as per completion of Neo-natal proforma (9am)

MONTH	LEVEL 2				
	Belfast Royal Jubilee	Northern Antrim	South Eastern Ulster	Southern Craigavon	Western Altnagelvin
Sep-10	130.90%	103.30%	162%	53%	55%
Oct-10	147.60%	66.10%	187%	58%	73%
Nov-10	130.90%	126.60%	112%	52%	49%
Dec-10	121.60%	88.70%	103%	81%	55%
Jan-11	121.10%	154.80%	126%	62%	54%
Feb-11	95.90%	114.30%	104%	85%	40%
Mar-11	89.40%	87%	76%	48%	43%
Apr-11	90%	108.30%	123%	66%	78%
May-11	104.60%	106.40%	74%	44%	48%
Jun-11	65.70%	38.30%	143%	56%	32%
Jul-11	82%	61.30%	74%	21%	61%
Aug-11	93%	74.20%	123%	48%	26%
Sep-11	74.70%	65%	72%	61%	47%
Oct-11	83.40%	96.80%	76%	27%	51%
Nov-11	117.60%	156.60%	140%	55%	25%
Dec-11	77.80%	91.90%	92%	33%	46%
Jan-12	93%	98.40%	187%	78%	49%

Figure 4(g): Occupancy Rates (%) by Level 2 Cot across Northern Ireland in 2011. Source: Information provided by HSC Trusts (February 2012)

	< 70%
	70%-94%
	> 94%

BELFAST TRUST: Notes. This information is an indicator and should be used indicatively only. When patients have not been discharged on the system i.e. a cot is apparently occupied by two patients at the one time. In specific regard to NICU there could also be issues in relation to the transfer between categories of levels of care i.e. there is quite a bit of transfer of babies between cots of differing levels of care which would exacerbate the issue.

SOUTHERN TRUST: CRAIGAVON Notes: % Occupancy Rate = Occupied Cots for each day in Month \ Available Cots by each day in Month. % Occupancy is a snapshot daily position as per completion of Neo-natal proforma (9am)

MONTH	LEVEL 3						
	Belfast Royal Jubilee	Northern Antrim	South Eastern Ulster	Southern Craigavon	Southern Daisy Hill	Western Altnagelvin	Western Erne
Sep-10	65.10%	104.60%	101%	98%	69%	77%	58%
Oct-10	27%	117.40%	98%	98%	44%	81%	77%
Nov-10	56.40%	98.30%	109%	105%	47%	68%	43%
Dec-10	50.10%	87.40%	116%	90%	49%	79%	83%
Jan-11	71.80%	79.70%	107%	124%	77%	85%	65%
Feb-11	88.50%	105.70%	95%	115%	71%	65%	68%
Mar-11	88.30%	114.80%	105%	124%	90%	70%	75%
Apr-11	78.40%	106.30%	79%	106%	67%	70%	43%
May-11	50.10%	103.50%	102%	71%	85%	86%	26%
Jun-11	67.10%	83.30%	70%	85%	75%	100%	23%
Jul-11	74.40%	83.50%	84%	84%	53%	49%	86%
Aug-11	65.80%	115.20%	96%	52%	78%	97%	41%
Sep-11	63.30%	113%	74%	81%	49%	84%	79%
Oct-11	72.20%	92.60%	61%	80%	56%	67%	37%
Nov-11	81.10%	92.30%	92%	71%	49%	49%	78%
Dec-11	96.10%	122.60%	103%	88%	72%	63%	71%
Jan-12	72.60%	109.40%	98%	52%	41%	49%	73%

Figure 4(h): Occupancy Rates (%) by Level 3 Cot across Northern Ireland in 2011. Source: Information provided by HSC Trusts (February 2012)

	< 70%
	70%-94%
	> 94%

BELFAST TRUST: Notes. This information is an indicator and should be used indicatively only. When patients have not been discharged on the system i.e. a cot is apparently occupied by two patients at the one time. In specific regard to NICU there could also be issues in relation to the transfer between categories of levels of care i.e. there is quite a bit of transfer of babies between cots of differing levels of care which would exacerbate the issue.

SOUTHERN TRUST: CRAIGAVON Notes: % Occupancy Rate = Occupied Cots for each day in Month \ Available Cots by each day in Month. % Occupancy is a snapshot daily position as per completion of Neo-natal proforma (9am)

SOUTHERN - DAISY HILL: % Occupancy is a snapshot daily position as per completion of Neo-natal pro-forma (9am). Total % Occupancy is different to Level 3 % Occupancy. The Total % includes cots occupied by Level 1 \ 2 babies, but there is no formal allocation of Level 1 \ 2cots.

4.5 Transfer Service

The neonatal transfer service is known as CONNECT and was established in October 2010. It operates from 09:00 until 18:00 hours Monday to Friday. After 18:00 hours, the sending hospital will contact the Northern Ireland Ambulance Service (NIAS) and the sending hospital will send their own staff to accompany the baby.

The CONNECT service also operates on Saturday and Sunday mornings (five hours) when it is nurse led. It is funded for 60 hours per week, for nursing and 40 hours per week registrar time. A 0.5 WTE Medical Consultant directs the service,

A medical consultant directs the service which is a joint neonatal and paediatric service.

CONNECT has its own dedicated ambulance and is part of the Northern Ireland Ambulance Service (NIAS) capital replacement programme. The service has its own incubator which the nursing staff are responsible for cleaning and there is a cleaning policy in place. According to IPCN staff in the Belfast Trust and the Southern Trust this was in place but needed to be updated. There is also a private ambulance service Aeromedics, which is used primarily by the Western Trust.

The CONNECT team has medical consultant and registrar input, as well as nursing input. The Co-ordinator is a nurse.

Approximately 560 babies have been transferred up until December 2011 (approx 40 transfers per month). The transfers include both planned and unplanned with back transfers (transfer back to originating hospital) of babies usually scheduled for Saturdays and Sundays. Many transfers (perhaps up to 200) are on site transfers from RJMS to other RVH sites such as the imaging centre or RBHSC.

The service provides training and study days for the region.

5. *Pseudomonas aeruginosa*

5.1 Introduction

Pseudomonas aeruginosa is a type of bacterium which is widely found in the natural environment. It is commonly found in soil and water and is particularly associated with wet and humid environments. It can survive in conditions that other bacteria are unable to. It can produce a biofilm which creates a protective layer when it grows in a water system. It requires a source of carbon in order to grow.

Pseudomonas aeruginosa rarely infects healthy individuals but can cause severe infection in patients who have underlying health problems such as cystic fibrosis, or burns. Pseudomonas can cause infections in different body systems including the skin, urinary tract, gut, respiratory system and blood. *Pseudomonas aeruginosa* can be found on the skin without necessarily causing infection, a situation known as colonisation.

Premature babies are very susceptible to infection with *Pseudomonas aeruginosa.* They have not yet developed their full immune system and have much less protection than full term babies from antibodies passed across the placenta from their mother. Very premature babies have delicate skin which can be damaged and infected very easily. Consequently, pseudomonas infection can have a devastating effect on the baby. These babies are also particularly at risk from colonisation of their respiratory system which can lead to severe infection. A premature baby is also frequently cared for in a humidified incubator, and *Pseudomonas aeruginosa* thrives in a humid environment.

5.2 Typing of Pseudomonas Bacteria

There are a very large number of different strains of *Pseudomonas aeruginosa.* New strains are continually occurring through genetic changes as the bacteria adapt to the environment. These strains can have different characteristics in relation to where and how they grow.

To identify related clusters of cases and outbreaks, it is important to be able to distinguish between the different strains. Linking strains from human and environmental sources can help to establish the source of an outbreak and possible methods of transmission.

There are differences in the genetic makeup of these different strains. Genetic testing (typing) can be carried out to identify strains to see if there is a relationship between cases of infection or between cases and environmental sources.

One method of testing is Variable Number Tandem Repeat typing (VNTR). The advantage of using this method is that there is a faster turnaround time compared to other methods of typing. Results are usually available within a day.

Every strain of *Pseudomonas aeruginosa* has a VNTR code which is a sequence of nine numbers. Number sequences for pseudomonas isolated from different sources can be compared when considering if cases or environmental sources are related.

5.3 Reporting of Pseudomonas

In Northern Ireland information on pseudomonas is based on voluntary reporting by hospital clinical microbiology laboratories to the Public Health Agency (PHA). At present only blood infections (bacteraemia) are reported.

In Northern Ireland, the number of reported cases of bacteraemia caused by pseudomonas has been gradually increasing over the past decade from 81 reports in 2001 to 113 reports in 2011. For babies under the age of one year, around one or two cases have been reported each year in Northern Ireland.

In the United Kingdom, from 2006 to 2008, there was an 8% increase in the number of *Pseudomonas* infections reported to the Health Protection Agency (HPA) (3,679 reports in 2006 compared with 3,957 reports in 2008), followed by a 4% reduction to 3,807 reports in 2010. Ninety-three per cent of these were *Pseudomonas aeruginosa*.

5.4 Pseudomonas and Water Systems

Domestic and hospital water systems are frequently colonised with pseudomonas with biofilms developing in pipework, taps and U-bends when there is a source of carbon to support growth.

Water distribution systems in hospitals and other large buildings are frequently complex networks and can be of considerable length. Dead ends, pipework subject to biofilm build-up, slow throughput, insufficient temperatures (below 55°C in the hot water pipes and above 20°C in the cold pipes) and infrequently used outlets all contribute to bacterial growth and making complete eradication of bacteria almost impossible. Pseudomonas is particularly likely to grow where there is stagnant water in the system which may occur if taps are not flushed regularly.

Several methods are used to reduce the possibility of pseudomonas infection in the water distribution system and also to prevent transmission to vulnerable patients. These include:

- ensuring that there are no areas of water stagnation resulting from low or limited use as this creates ideal conditions for growth of pseudomonas
- flushing all taps regularly in wards that contain vulnerable patients
- maintaining hot and cold water at the correct temperatures – cold water below 20°C and hot water above 55°C
- ensuring best practice in relation to infection control

There has been considerable debate regarding which design of tap is most likely to protect the water system from bacterial contamination. In many healthcare settings, sensor taps have been introduced as the no-touch operation reduces the risk of spread of infection through touching tap surfaces.

However, sensor taps have internal components which may support pseudomonas growth if they contain carbon. Also, there has been concern that low flow rates increase the risk of the growth of pseudomonas.

Following blending of hot and cold water supplies by a thermostatic mixer valve, water will be supplied for use at 41°C providing an environment in which pseudomonas bacteria can multiply. The position of such thermostatic mixer valves will vary, some will be integral with the mixer tap and others sited upstream of the tap.

5.5 Outbreaks of *Pseudomonas aeruginosa* Linked to Neonatal Units

Pseudomonas aeruginosa has been a known risk cause of outbreaks in neonatal care settings for over 50 years[4]. Investigations of outbreaks have linked causes to different factors including contaminated equipment[5], staff fingernails [6], use of water baths to thaw frozen plasma [7], hand hygiene[8], contaminated feeding bottles[9] the use of expressed breast milk for feeding[10] and contamination of a dextrose multidose vial[11].

There have been a number of reports about electronic sensor taps becoming colonised by *Pseudomonas aeruginosa.* In November 2011, a report was published from Turkey that an outbreak affecting 12 babies in a neonatal intensive care unit was probably due to contamination of electronic sensor taps.[12]

[4] Jellard CH, Churcher GM. An outbreak of *Pseudomonas aeruginosa (pyocyanea)* infection in a Premature Baby Unit, with observations on the intestinal carriage of *Pseudomonas aeruginosa* in the newborn. *J. Hyg.,Camb (1967);65,219-228*

[5] Garland SM et al. *Pseudomonas aeruginosa* outbreak associated with a contaminated blood-gas analyser in a neonatal intensive care unit. *Hosp infect. (1966); 33:145-51*

[6] Moolenaar et al. A prolonged outbreak of *Pseudomonas aeruginosa* in a neonatal care unit: did staff fingernails play a role in disease transmission? *Infect.Control Hospt Epidemiology 2000;21 80-85*

[7] Muyldermans G et al. Neonatal infections due to *Pseudomonas aeruginosa* associated with a water-bath used to thaw fresh frozen plasm. *J.Hosp Infect. 39:309-14*

[8] Crivaro V et al. *Pseudomonas aeruginosa* in an neonatal intensive care unit: molecular epidemiology and infection control measures. *BMC Infectious Diseases 2009. 9:70*

[9] Sanchez-Carrillo C et al. Contaminated feeding bottles: the source of an outbreak of *Pseudomonas aeruginosa* infections in a neonatal intensive care unit. *Am J Infect. Control 2009; 37 150-4*

[10] Mammina C. et al. Nosocomial colonisation due to imipenem-resistent *Pseduomonas aeruginosa* epidemiology linked to breast milk feeding in a neonatal care unit. *Acta Pharmacol. Sin 2008 29 (12) :1486-92*

[11] Archibald LK et al. *Enterobacter cloacae* and *Pseudomonas aeruginosa* polymicrobial bloodstream infections traced to extrinsic contamination of a dextrose multidose vial. *J. Pediatr.1998 Nov;133(5):640-4.*

[12] Yapicioglu H et al. *Pseudomonas aeruginosa* infections due to electronic faucets in a neonatal intensive care unit. *J Pediatr Child Health* 2011;Nov 16 E-pub.

6. Chronology Overview

6.1 Introduction

In order to understand the complex sequence of events in the period leading up to and during the pseudomonas incidents, each organisation was asked to prepare a timeline of relevant events for the period from 15 September 2010 to 31 January 2012.

The timelines and supporting evidence have been considered by the Review Team and an outline of the key events is set out below.

This overview has been divided into six sections to facilitate understanding:

- Issue of relevant circulars and advices by DHSSPS
- Outbreak at Altnagelvin Neonatal Unit
- Outbreak at Royal Jubilee Maternity Service (RJMS) NICU
- Cluster of cases associated with Craigavon Hospital Neonatal Unit
- Cases linked to Antrim Hospital Neonatal Unit
- Regional response following the declaration of RJMS outbreak

6.2 Issue of Relevant Circulars and Advices by DHSSPS

DATE	CIRCULAR / ADVICE ISSUED BY DHSSPS
15 September 2010	Circular **HSS (MD) 34/2010,** was issued to HSC Trusts for action. The circular contained interim advice which had been provided to NHS Trusts in England in a letter issued by the Department of Health on 27 August 2010. Further investigation was taking place in England. **HSS (MD) 34/2010** advised trusts that DHSSPS had become aware of reports from England and Wales of outbreaks of infection caused by pseudomonads. The incidents had occurred in in augmented care wards, (such as adult or neonatal intensive care, renal and burns units) and 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.

1 July 2011	A Professional Estates Letter, **PEL(11)13,** was issued to HSC organisations for action. The letter provided a summary of the key outcomes of a workshop held in 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 healthcare 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 dead legs within the hot and cold water systems as part of ongoing system maintenance. Chief Executives were to provide a statement of assurance, by 31 August 2011, that written schemes had been reviewed.
23 August 2011	An alert notice, **NIA-2011-002,** was issued by the Northern Ireland 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.
22 December 2011	A 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.

22 December 2011	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).
28 January 2012	A circular, **HSS (MD) 4/2012,** was issued to HSC Trusts, the Public Health Agency and the HSC Board providing interim guidance on pseudomonas and neonatal units. This guidance had been developed in consultation with the Health Protection Agency 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 babes 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.

The Review team has received evidence on the actions taken by HSC organisations in relation to the circulars and advices outlined above. This will be considered in the final report of the review.

6.3 Outbreak at Altnagelvin Hospital Neonatal Unit

DATE	ACTION
26 November 2011	A baby being cared for in the ICU room of Altnagelvin Neonatal Unit had a urine specimen sent for testing. Two days later this was reported to be positive for *Pseudomonas aeruginosa.* The baby developed pseudomonas infection of the skin and blood cultures were sent for testing. On 2 December 2011, the baby was transferred from Altnagelvin to RJMS NICU in Belfast for treatment of another condition. The blood cultures were reported to be positive for pseudomonas on 4 December 2011 and this information was passed by phone from Altnagelvin laboratory to RJMS NICU on that day.

6 December 2011	The condition deteriorated of a second baby in the ICU room, who had been very unwell since birth. Blood cultures were taken and, on 8 December 2011, were reported by the laboratory to be positive for *Pseudomonas aeruginosa.* The baby did not respond to treatment and died on 10 December 2011.
10 December 2011	A third baby being cared for in the ICU room developed signs of infection and a decision was taken to treat the baby for a presumed diagnosis of pseudomonas infection. Preliminary blood culture results on 11 December 2011 indicated that the baby had a bacterial infection of the blood and this was confirmed as *Pseudomonas aeruginosa* on 12 December 2011.
12 December 2011	The Altnagelvin Infection and Prevention Control (IPC) team informed the Western Trust Medical Director about the cases of infection with pseudomonas. The Medical Director convened an Incident Control Team (ICT) meeting that day to review the facts, confirm appropriate infection control measures were in place and co-ordinate on-going investigations. A series of actions was agreed including environmental sampling, observation of practice, checking the ventilation system, a terminal clean of the ICU room and arrangements for talking to parents. Following the meeting, the PHA was informed of the outbreak through contact with the on-call Specialist Registrar who subsequently informed the on-call Health Protection Consultant and Director of Public Health that three babies had pseudomonas infection and that one had died.
13 December 2011	The Western Trust Medical Director briefed the Trust Chief Executive and the Deputy Chief Medical Officer (CMO) at DHSSPS. The Deputy CMO referred the Western Trust Medical Director to the guidance issued in September 2010 in **HSS (MD) 34/2010.** The Deputy CMO subsequently informed the CMO that day and a submission was prepared to brief the Minister about the pseudomonas incident. The CMO asked colleagues for advice as to whether to re-issue **HSS (MD) 34/2010**. The Deputy CMO advised Health Estates Investment Group (HEIG) who made contact with the WHSCT head of infection control and a member of estates staff. The PHA nominated three members of staff to join the Incident Control Team in WHSCT. These staff attended the ICT meeting to offer support and advice on control measures and investigation. The ICT met again and was attended by representatives from the PHA. The ICT was advised that the ICU room, in which the three babies had been located, had been used intermittently and babies were normally placed in two cots at the front of the room.

13 December 2011	During this period, babies had also been looked after at the back of the room. The sink at the back of the room was not frequently used and swabs from this sink had shown heavy growths of pseudomonas. Tap water was being used during nappy changes hitherto a common practice in the UK. A paediatric consultant informed the ICT that she had been advised that there was a second baby with pseudomonas in RJMS NICU as well as the baby who had transferred from Altnagelvin. Actions agreed by the ICT included; contact with RJMS by the PHA and the Western Trust Head of Infection Control; contact with the transfer service who had brought the baby from Altnagelvin to RJMS; flushing of taps in all augmented care wards[13]; sterile water to be used at all times for all babies in ICU and High Dependency Unit (HDU); no water to be used from the taps in ICU.
14 December 2011	A Serious Adverse Incident form was submitted to the HSCB by WHSCT. At the daily ICT meeting, the Health Protection Consultant from PHA presented advice from the HPA that screening of babies in NICU for both pseudomonas and MRSA should be carried out on a weekly basis. The Western Trust agreed to start this on Monday 19 December. Samples were sent from Altnagelvin to the HPA reference laboratory for analysis of the strains of *Pseudomonas aeruginosa.* HEIG e-mailed WHSCT head of Operations and Maintenance re-iterating the practice contained within HSS(MD) 2010. The CMO decided that a further circular should be issued to HSC organisations to highlight estates and infection control aspects. This was discussed at a teleconference between the DHSSPS and a Consultant in Health Protection at PHA.
15 December 2011	The ICU room which had the tap positive for pseudomonas had the infected tap and associated thermostatic mixer valve (TMV) replaced. The water system was chlorinated, retested and found to be clear. A terminal clean was carried out for the ICU room. The Western Trust ICT was informed that preliminary results of the strain typing of the two babies in RJMS ICU indicated they had different strains. The Western Trust shared this information with a Senior Medical Officer at DHSSPS during a briefing on the outbreak on the following day.

[13] The operational definition of augmented care at that time (in the absence of regional guidance) was: Adult intensive care/high dependency; Neonatal units; Oncology.

21 December 2011	A temporary relocation of the Neonatal Unit took place to enable a completed disinfection of the water system to proceed. Antimicrobial paint was applied to the walls during this period. The Western Trust responded to a press enquiry in relation to the death of a baby. The trust did not confirm any details to protect confidentiality but did issue a statement which included the information that: "The Trust can confirm that there was an uncommon infection caused by Pseudomonas in early December 2011 at Altnagelvin Hospital's Neonatal Intensive Care Unit. All the necessary infection prevention and control measures were put in place and the infection has now been eradicated." This story was reported in a local paper.
22 December 2011	**HSS(MD) 31/2011** was issued by DHSSPS – received by WHSCT by e-mail and circulated to relevant officers within the trust on the following day. A preliminary verbal report was received from the HPA Reference Laboratory which suggested that two of the three babies infected in Altnagelvin NICU had the same strain of pseudomonas as the contaminated tap in the ICU room. One baby appeared to have a different strain. These results were confirmed in writing on 30 December 2011. The strain leading to infection in one baby was subsequently found from a swab taken from a sink at the front of the ICU room on 12 January 2012.
5 January 2012	The outbreak of pseudomonas in Altnagelvin NICU was discussed at a meeting of the PHA Regional Protection Advisory Forum attended by representatives from some trusts.
12 January 2012	The results of the fourth weekly screen of babies for pseudomonas showed that two babies had colonisation with pseudomonas. The previous screens had all been negative. Environmental swabs were repeated.
16 January 2012	The results of the environmental swabs were reviewed and two taps were positive for pseudomonas. Neither of these taps had been positive when tested three times previously.
20 January 2012	A Western Trust Incident Review Team met to review the management of the incident and the results of the screening of babies and the environment. The team then became aware of the Belfast Trust outbreak.
Period following 20 January 2012	The Western trust participated in the regional processes following the declaration of the outbreak at RJMS ICU and took forward agreed actions at local level. There were no further infections or colonisations with pseudomonas of babies reported from Altnagelvin Neonatal Unit in the period up to 31 January 2012.

In summary, an outbreak of infection caused by *Pseudomonas aeruginosa* occurred in Altnagelvin Neonatal Unit between 26 November 2011 and 10 December 2011. This caused infection of three very pre-term babies of whom one died. All three babies had been nursed in the ICU room of the 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 been 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, two babies were found to have colonisation with *Pseudomonas aeruginosa*, through a weekly screening programme established following the outbreak.

6.4 Outbreak at Royal Jubilee Maternity Service Neonatal Unit

DATE	ACTION
2 December 2011	A baby, known to have *Pseudomonas aeruginosa* of the skin, was transferred from Altnagelvin NICU to RJMS NICU for treatment of another condition (Section 6.3). Blood cultures, taken in Altnagelvin, were reported to be positive for *Pseudomonas aeruginosa* on 4 December 2011 and this information was passed by phone from Altnagelvin Hospital to RJMS NICU on that day.
6 December 2011	A baby in RJMS NICU, who had been born in RJMS, had respiratory secretions sent to the laboratory. These were confirmed to be positive for *Pseudomonas aeruginosa* on 8 December 2011.
8 December 2011	A medical microbiologist informed an Infection Prevention Control (IPC) Nurse at Belfast Trust that there were two babies in NICU with pseudomonas in the unit. Two IPC nurses visited NICU and recommended that the two babies should be co-located (nursed together to minimise risk of spread to other patients). The IPC nurses provided advice on cleaning and bed spaces were cleaned to facilitate the co-location of the two babies. The nurses noted that the roof of the unit was leaking and a sample of water was obtained. On advice from microbiology this was not processed. The IPC nurse was advised on 9 December by the Estates Department that the required repairs were being dealt with.
9 December 2011	The *Pseudomonas aeruginosa* isolates from the two babies were sent to the HPA Reference laboratory in England for typing due to concern that there had been two cases of pseudomonas within one week in the unit.

13 December 2011	An IPC nurse visited NICU to ensure that the contact precautions for the two babies were in place. A consultant neonatologist and the NICU Manager at RJMS were advised of an outbreak of pseudomonas at Altnagelvin Hospital through a phone call from a paediatrician there.
14 December 2011	An IPC nurse from Altnagelvin contacted the IPC team in Belfast Trust by email to advise of the outbreak there. The Altnagelvin IPC nurse advised that a sink was the possible source of the infection. A consultant at PHA contacted the Belfast Trust IPC doctor about the baby from Altnagelvin who had transferred with pseudomonas. The IPC doctor advised the PHA consultant that respiratory secretions from another baby in RJMS had tested positive for pseudomonas.
15 December 2011	Preliminary typing results from the HPA Reference Laboratory indicated that the strains of pseudomonas for the two babies in RJMS were different. As there was no evidence for spread of infection between the babies, the infection in the baby born in RJMS was considered to have been sporadic. The Belfast Trust advised the PHA of the preliminary typing results and an SAI form was not submitted.
16 December 2011	PHA advised Belfast Trust directors at the Belfast Trust performance meeting with PHA and HSCB of the outbreak of pseudomonas at Altnagelvin NICU. The cases in RJMS NICU were also discussed. A Senior Medical Officer in DHSSPS advised the CMO and colleagues in DHSSPS by email that, following typing, the two cases in RJMS were unrelated as they had different strains.
22 December 2011	**HSS(MD) 31/2011** was received by email in the Belfast Trust and circulated to relevant officers within the trust on the following day.
29 December 2011	The Belfast Trust Director of Nursing received advice from the Trust IPC Doctor that **HSS(MD) 31/2011** would be considered at the next meeting of the trust Water Safety Group on 24 January 2012.
5 January 2012	A baby in RJMS NICU developed respiratory symptoms and a specimen was sent for testing. This was reported as possible *Pseudomonas aeruginosa* on 6 January 2012. The baby's condition deteriorated rapidly and the baby died later that evening. Blood cultures taken on 6 January 2012 subsequently grew *Pseudomonas aeruginosa* which was reported on 8 January.
9 January 2012	The Medical Microbiology Team requested that the isolate from the baby should be prepared to be sent for typing in view of concern about a possible outbreak. A decision was made to expedite typing rather than escalate and call an outbreak. NICU was visited by a medical microbiologist and an infection Control Nurse who provided advice on de-cluttering and cleaning.

10 January 2012	The medical microbiologist was informed by the clinical team in RJMS NICU that they had heard there was a baby in Craigavon Area Hospital (CAH) NICU who had bacteraemia caused by *Pseudomonas aeruginosa.* The medical microbiologist contacted the laboratory at CAH and was provided with information about the investigation results for the baby.
11 January 2012	The RJMS medical microbiologist discussed the information about the baby in CAH with the RJMS Trust IPC Doctor and considered it was probable that the infection had been acquired in CAH.
13 January 2012	Belfast Trust contacted the HPA Reference Laboratory to emphasise urgency and expedite typing for the sample which had been sent. A baby in RJMS was diagnosed with ventilator acquired pneumonia. This baby had been born in Daisy Hill Hospital and transferred to RJMS via Craigavon Hospital. Respiratory secretions were sent for analysis. The baby's condition did not respond to treatment and the baby died on 14 January 2012. On 15 January 2012, the respiratory secretions and blood cultures taken on 14 January 2012 were both reported as positive for *Pseudomonas aeruginosa.*
16 January 2012	Blood cultures were obtained from a baby in RJMS NICU who required to be ventilated that day. On 18 January 2012 *Pseudomonas aeruginosa* was isolated. The baby's health continued to deteriorate despite treatment and the baby died on 19 January 2012. The HPA Reference Laboratory phoned Belfast Trust at 18:15 to advise that the strain of pseudomonas from the baby who died on 6 January 2012 was identical to the strain found in the baby from whom samples had been taken on 6 December 2012 in RJMS NICU. An incident meeting was arranged for the following day.
17 January 2012	An incident meeting was held at which the outbreak was confirmed. Initial control measures were established which included: restricting admissions to NICU; co-locating affected infants; environmental sampling to include potential habitats of pseudomonas especially taps and water; alcohol rubs immediately after hand washing; sterile water for nappy changes; screening all other infants; expediting typing for babies who had been infected on which this had not yet been carried out. Following the incident meeting, PHA was informed by the Belfast Trust of the outbreak. The trust sent an Early Alert notification to the DHSSPS about the incident and reported it as an SAI on the following day. The Chief Executive was briefed on the situation by the Director of Specialist Hospitals and Women and Child Health.

18 January 2012	An isolate was cultured from the sputum of a baby in the unit which was subsequently confirmed as *Pseudomonas aeruginosa.*
19 January 2012	A meeting of the Belfast Trust Outbreak Control Team was held. The OCT was advised that further information on strain typing was now available and the strain of *Pseudomonas aeruginosa* cultured from samples from the baby who died on 14 January 2012 was different to the other strains which had been identified. 4 babies had been found to be colonised with *Pseudomonas aeruginosa* through the screening exercise carried out on 16 January 2012. Environmental sampling had detected pseudomonas in swabs from two taps in NICU and another tap was likely to be confirmed positive. The OCT agreed further control measures including taking action to move babies out of the unit so that it could be subjected to intensive cleaning. The OCT agreed to issue a press release that day in relation to the outbreak. A helpline was established by Belfast Trust that evening.
20 January 2012	A press conference was held in the Belfast Trust in which the Minister and CMO and PHA participated in relation to the outbreak. NICU was closed and babies moved to other rooms in the Regional Neonatal Unit. Following replacement of wash hand basins and sensor taps, the unit was reopened on 6 February 2012. Following the declaration of the outbreak the OCT continued to meet to manage the outbreak and trust staff participated in regional teleconferences and meetings. Helpline established by Belfast Trust and announced at a press conference.
24 January 2012	Typing results from the HPA Reference Laboratory confirmed that the baby who had been diagnosed within CAH with pseudomonas from a positive blood culture taken on 29 December 2011 had the same strain as had caused the outbreak in Belfast. The results also confirmed that the baby who had died in RJMS on 19 January 2012 had the same strain. A meeting was held for parents of babies in the unit to provide them with information about the outbreak.

Following the establishment of a review of the epidemiology of the NICU outbreaks by PHA, important additional information has emerged as to the distribution of infections and colonisations with *Pseudomonas aeruginosa.* This will be considered further in the final report of the review. The Review Team has been provided with an interim analysis which has reported the following preliminary findings in relation to the outbreak at RJMS NICU:

- In total there were five cases of infection and 10 colonisations associated with the strain of pseudomonas linked to the Belfast outbreak. Three of the babies died. For one baby pseudomonas was not the reported cause of death.

- The baby who died in RJMS on 14 January 2012 had a different strain which was subsequently found in three babies who were colonised and were in Craigavon Area Hospital.

- Two babies who were initially screened negative in RJMS were found to be positive with the strain associated with Belfast when they were rescreened on transfer to Antrim and Craigavon Hospitals
- *Pseudomonas aeruginosa* of the same strain as the babies in the Belfast outbreak was detected in water samples taken from hand washing taps in RJMS in both NICU (4 taps out of 6) and SCBU (1 tap out of 6).
- The earliest sample of *Pseudomonas aeruginosa* which has been epidemiologically linked to the Belfast strain was taken on 15 November 2011 in a baby who was transferred from RJMS to Craigavon Area Hospital and who subsequently was found to have the strain linked to Belfast when a subsequent sample was taken on 26 January 2012. A further colonisation was detected in a baby in RJMS on 21 November 2011 and was subsequently found when screened on 20 January 2012 in Daisy Hill Hospital to have the strain associated with Belfast.

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, in the period subject to this review.

6.5 Cluster of Cases Associated with Craigavon Hospital Neonatal Unit

DATE	ACTION
22 December 2011	**HSS (MD) 31/2011** was received by Southern Trust and circulated to relevant directors and staff.
29 December 2011	A baby in Craigavon Neonatal Unit had blood cultures taken which subsequently were found to be positive for *Pseudomonas aeruginosa.* The baby had been born in RJMS and initially cared for in RJMS NICU before transfer to Craigavon on 23 December 2011. The baby died in January 2012. Pseudomonas was not the reported cause of death. This baby was later found to have had the strain of pseudomonas linked to RJMS NICU in Belfast.
14 January 2012	In keeping with routine practice, RJMS NICU contacted Craigavon NICU and advised of the death of a baby that day who had been previously in Craigavon Neonatal Unit.
16 January 2012	A microbiologist at Craigavon was contacted by a microbiologist from Belfast Trust regarding 2 babies from Craigavon who had been transferred to RJMS. She asked if Craigavon had had any problems with pseudomonas bacteraemia or colonisation in the past year. The Craigavon microbiologist contacted the Trust Clinical Director of Infection Prevention and Control.

17 January 2012	The Southern Trust Lead Infection Control Nurse contacted the Belfast Senior Infection and Prevention Control Nurse to seek information and clarity with regard to pseudomonas in RJMS. The Lead ICN informed the Clinical Director and IPC Team and the Medical Director was subsequently informed.
18 January 2012	The Clinical Director and Lead ICN visited Craigavon Neonatal Unit. It was agreed to include pseudomonas in routine screening of babies from other units. The isolation of transferred babies until screening results were available was standard practice in the unit. Enhanced monitoring and IPC precautions were reinforced.
20 January 2012	All babies in Craigavon Neonatal Unit and Daisy Hill SCBU were screened for pseudomonas. A baby was transferred to Craigavon Neonatal Unit from RJMS NICU who was screened for pseudomonas and was reported to be positive on 22 January 2012. Subsequently this was found to be the strain associated with Belfast.
21 January 2012	Provisional results of swabs for screening indicated probable positive results for 2 babies in Craigavon Neonatal Unit and one in Daisy Hill SCBU. Additional nurse staffing was provided to establish 1:1 cohort nursing and isolation for all colonised infants. Sterile water for washing of babies was implemented in both the neonatal unit and SCBU following a conversation between the Lead ICN and a colleague in Belfast Trust.
22 January 2012	The provisional results from the previous day were confirmed. The baby in SCBU had been transferred from the Royal Belfast Hospital for Sick Children, having been earlier in RJMS and was subsequently found to have the strain associated with Belfast.
23 January 2012	A Control Team Meeting was held and a programme of further actions particularly relating to risk management of sinks/water and enhanced cleaning was agreed for immediate implementation.
24 January 2012	A third infant in Craigavon Neonatal Unit was confirmed positive for pseudomonas colonisation from the screening of babies which had taken place on 20 January 2012.
26 January 2012	At 19:30 the Clinical Director for Infection Prevention and Control was telephoned by the Belfast IPC Doctor. The IPC Doctor advised that a baby who had been transferred from Craigavon to RJMS NICU in early January, and who had subsequently died, had a strain of *Pseudomonas aeruginosa* which was not the strain linked to Belfast and was possibly a Craigavon strain.
27 January 2012	Given the strain information, PHA held a teleconference with HPA, spoke to the Southern Trust that evening and produced and issued guidance on further actions to be taken. The trust Chief Executive confirmed to the DPH that an Incident Control Team would meet the following morning, the Chief Executive would chair that team and that all additional actions required by the PHA would be taken.
28 January 2012	A Pseudomonas Incident Team was convened, attended by PHA representatives. All recommended actions were reviewed and considered to be in place.

The interim findings of the epidemiology study being carried out by the PHA indicate that one baby was infected and three babies were colonised with the same strain of *Pseudomonas aeruginosa* which has been linked to Craigavon Neonatal Unit. The baby who was infected with the strain spent several hours in the unit awaiting transfer to RJMS from Daisy Hill. The baby later died in RJMS NICU. A further baby developed bacteraemia while being cared for in Craigavon Neonatal Unit, having being transferred from RJMS. This baby had the strain of pseudomonas which has been linked to Belfast. A number of different strains of pseudomonas have been found in swabs taken from taps and sinks 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 infection and colonisations.

6.6 Cases Linked to Antrim Hospital Neonatal Unit

Two babies were found to be colonised at Antrim Neonatal Unit through screening.

DATE	ACTION
20 January 2012	A baby screened on admission to the unit was found to be positive for *Pseudomonas aeruginosa.* This baby had been transferred from RJMS Neonatal Unit and was subsequently found to have the strain linked to Belfast. The baby had screened negative in Belfast on 17 January 2012.
24 January 2012	A baby screened in Antrim Neonatal Unit was found to be positive who had only been cared for in Antrim. This strain has, to date, been found to be unique and has not been linked to any of the human or environmental strains associated with these incidents.

Environmental sampling from two sinks and water samples from taps in Antrim neonatal unit were found to be positive for *Pseudomonas aeruginosa.*

6.7 Regional Response following the Declaration of RJMS Outbreak

DATE	ACTION
17 January 2012	PHA was informed by Belfast Trust that babies in the neonatal unit had pseudomonas, of whom two had died. PHA offered support and advice to the Belfast Trust on control measures to be put in place and on the need to draw on learning from Western Trust. DHSSPS received Early Alert from Belfast Trust that two babies were confirmed with same strain of pseudomonas infection, of whom one baby had died. Trust awaiting results on two other babies of whom one had died. Admissions to the unit were to be restricted.

18 January 2012	DHSSPS prepared a submission for the Minister advising of outbreak at RJMS. SAI notification form was submitted by Belfast Trust to HSCB concerning outbreak at RJMS.
19 January 2012	PHA representatives attended the Belfast Trust Outbreak Control Team (OCT) meeting. DHSSPS briefed by PHA on the incident. Minister issues press release offering sympathy to the families of the two young babies who had died at RJMS. A third baby died in RJMS neonatal unit during the night who had pseudomonas.
20 January 2012	PHA held a teleconference with Belfast Trust at 09:30. HSCB chaired a later teleconference with all trusts, the Minister, DHSSPS, and PHA to discuss how to manage the capacity of neonatal cots across Northern Ireland. PHA contacted the regional neonatal transfer service and Northern Ireland Ambulance Service. Guidance on health protection advice when transferring babies between units was discussed with trust clinical staff and issued to trusts by PHA. Press conference held with Minister and CMO joining Belfast Trust and PHA representative. Minister issued a press release following death of the third baby at RJMS and CMO and Minister provided interviews for media.
21 January 2012	PHA representatives attended the Belfast OCT meeting PHA held a teleconference with HPA to seek advice as to whether to start weekly screening of babies. HPA advised a risk based approach based on pattern of cases and colonisations. Regional teleconference was held with all trusts and guidance given on transfer of minimising neonatal transfers, transferring in utero when possible and screening babies before and after transfer between units. Decision taken during teleconference that sterile water should be used for all washing of babies during nappy changes.
22 January 2012	PHA and HSCB agreed that PHA should lead the joint response as issues were primarily related to public health rather than service delivery. The DPH was nominated as Incident Lead Director. PHA/HSCB/BSO activated their Joint Response Plan in relation to incidents. They agreed to establish an Emergency Operations Centre. Plans were developed for a regional epidemiological investigation to be carried out.

22 January 2012	A teleconference was held between with HPA, Belfast Trust and PHA to discuss issues relating to water and taps. The daily regional conferences were now formally regarded as meetings of the Regional Health Response Group (RHRG), CMO and Senior Medical Officer from DHSSPS participated.
23 January 2012	Joint Emergency Operations Centre was established. PHA recommended that Belfast Trust OCT set up a sub-group to provide assurance that all control measures were implemented. PHA issued guidance to trusts on management of colonised babies, screening and infection control measures. At RHRG, Belfast Trust advised that samples of 4 out of 6 sinks in NICU were presumptive positive results. DHSSPS advised Belfast Trust that tap replacements should be with manual lever operated taps without thermostatic mixer valves. DHSSPS informed UK estates organisations of the outbreak with request for advice if available. Minister issues press release to advise that 6 babies in RJMS were confirmed to have pseudomonas infection and one more potentially infected. Minister provides update at Oral Questions in NI Assembly.
24 January 2012	Minister gave detailed statement to the NI Assembly on the outbreaks. Minister and CMO facilitated media interviews. A press release was issued that the case of infection from previous day was now confirmed. PHA and DHSSPS initial teleconference was held to consider the need to test water and replace taps based on the balance of risk. PHA teleconference was held with trusts to go through guidance issued on 23 January.
25 January 2012	PHA visited RJMS to explore the potential to increase capacity in the neonatal unit. Liaison took place between PHA and HPA Board with regard to management of the incident. CMO wrote to CMO (England) to ask that specific areas in national report on potential risks from pseudomonas were prioritised for action to protect vulnerable patients. CMO convened a conference call with PHA to discuss Point of Use Filters and taps.

26 January 2012	Joint Response Incident Control meetings were established given the potential that the incident could impact on other neonatal units. A teleconference took place between PHA, DHSSPS, and Belfast Trust to discuss use of Point of Use filters. Further DHSSPS/PHA teleconference on water testing and replacement of taps in other units. It was determined that further guidance should be issued by the DHSSPS. PHA issued further guidance to trusts with updated guidance on case definitions, reporting requirements and screening.
27 January 2012	CMO formally requested expert advice and support from the HPA. PHA held teleconference with trusts re environmental risk assessment guidance. During daily RHRG teleconference the decision to use sterile water for bathing or toileting infants was confirmed. PHA issued guidance for GPs and paediatric doctors as to why discharged babies do not need to be followed up. PHA held a teleconference with HPA to discuss emerging strain typing results. Advice was issued to Southern and Northern Trusts in view of the results. CMO held a teleconference with Trust Medical Directors and requested information on response to DHSSPS guidance letters.
28 January 2012	DHSSPS and PHA met to agree final guidance on water sampling and tap replacement programme. CMO convened a teleconference with trusts, the PHA and HSCB to review the situation. CMO convened a teleconference with HPA and PHA to agree interim protocol for water testing. PHA and South Eastern Trust held a teleconference to discuss presumptive positive results from taps in neonatal unit. PHA advised that babies should remain in the unit with control measures and regular screening of babies and water sampling. Minister issued a statement about situation in South Eastern Trust CMO provided updates to Minister, Permanent Secretary, Chair and Deputy Chair of Health Committee.

28 January 2012	DHSSPS guidance HSS (MD) 4/2012 issued to trust Chief Executives. Site visit by PHA to NHSCT to discuss and seek assurances in respect of advice issued on evening of 27 January.
29 January 2012	PHA issued guidance to trusts on the process for reporting tap replacements and water sample results to PHA. PHA provided information for trusts to use for parents which would explain the need for water sampling. DHSSPS and HPA agreed to hold a teleconference to discuss the protocol for scientific testing of taps at Porton Down. CMO gave live interview on the current situation.
30 January 2012	DHSSPS shared interim guidance with other UK CMOs. Health Estates agreed to establish a Regional Water Group to oversee tap replacement programme. Arrangements put in place for a daily teleconference between HEIG, trusts and PHA on tap replacement programme. PHA agreed on-site visits to neonatal units to collect information for epidemiology investigation. Minister asked RQIA to facilitate an independent review.
31 January 2012	Minister gave a second statement to the NI Assembly on pseudomonas in neonatal units followed by press interviews. CMO held a teleconference with other UK CMOs to discuss pseudomonas in neonatal units in Northern Ireland. This meeting included Chair of Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI). ARHAI was asked by CMO to provide advice on pseudomonas in all augmented care settings. HPA initiated a teleconference with PHA and Health Estates to discuss scientific examination of taps to inform the national evidence base. PHA issued further guidance recommending twice weekly screening of babies in neonatal units and screening when babies are transferred from other units. RHRG conference call. Altnagelvin reported presumptive positive water tests. Belfast Trust reported a Pseudomonas colonised baby in their paediatric ICU who had been in RJMS neonatal unit. PHA carried out a risk assessment and advised that screening of others in the unit was not required. HPA/PHA teleconference was held to review information related to Craigavon neonatal unit.

7. The Family Perspective

In recognition of the tragic impact of pseudomonas infection for the families of those babies who have been affected, it was decided that during the course of the review the parents of those babies affected should be engaged with directly.

A letter was sent, through the trusts, to parents of babies that had been affected by pseudomonas offering to meet with them. It was felt that it was extremely important to hear the views of families as they might have information that was relevant to the review and also they may have questions that they felt should be answered.

The review team has met with eight families so far. For the purposes of this interim report the following is a combined short account of the experiences they shared with review team members during the meetings. A more detailed account of the issues arising will be included in the final report.

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 would be made to try to prevent such an outbreak happening again. The review team recognises that this was a very difficult subject to discuss and wishes to thank all those involved for their participation, openness and willingness to share their experiences.

Generally families were initially positive regarding how they were treated by medical and nursing staff. They were very positive about the clinical care their babies had received, however after some discussion some issues regarding communication and passing on of information began to emerge.

In most cases it was felt that nursing staff were good at passing on information regarding babies' care and they provided useful help with regard to feeding and caring for babies. In one case it was felt that the transfer team had looked after a baby as if it was their own and in another, the family felt that their baby had been looked after by the "A team."

However there were some reservations regarding the passing on of information from some medical staff as they tended to use language that was too technical.

The families were asked about what effect they felt the outbreaks had on staff and they realised that there had been a big impact on staff who had been noticeably upset and stressed. They also realised that in many cases nursing staff were upset and hurt by the fact that babies in their care were sick.

When asked about when and what they were told about pseudomonas some of the families felt that they had not been sufficiently informed about the seriousness of their babies' condition.

When asked about infection control procedures in neonatal units all families noted that they felt that infection control procedures had been good. They also had been given instructions on washing hands and being bare below the elbows.

There is still an opportunity for families to engage with the review team if they wish in advance of the final report.

8. Interim Findings and Conclusions

8.1 Introduction

The Terms of Reference for this review requested an interim report to be submitted to the Minister by 31 March 2012 to enable any immediate actions identified to be taken forward as soon as possible.

The review team has been made aware during phase one of this review of a number of important exercises that are underway at national and regional levels and will be relevant to the final report of this review. These include:

- Water Sources and potential *Pseudomonas aeruginosa* Infection of Taps and Water Systems: Advice for augmented care units: Department of Health which was published on the Department of Health (England) website on 30 March 2012.
- The UK Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) has established a sub-group to advise on the management of infections in neonatal units.
- Taps which were removed from neonatal units across Northern Ireland have been sent for analysis by the Health Protection Agency laboratory at Porton Down.
- Collection of further information about pseudomonas incidents in augmented care settings across England by the Health Protection Agency.
- The Public Health Agency is completing an epidemiological investigation of the pseudomonas incidents in Northern Ireland.
- Belfast Trust is completing a root cause analysis of the circumstances leading to the pseudomonas outbreak in the neonatal unit at Royal Jubilee Maternity Service.

The review team has met with the PHA team carrying out the epidemiological investigation. The information provided has been helpful in understanding the complex pattern of the events which have occurred.

The review team has received a briefing on the emerging findings from the Belfast Trust root cause analysis, which closely mirrors the interim conclusions reached independently by RQIA's review team.

The findings and conclusions set out in this interim report focus on the first two terms of reference for the review:

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.

The final report, to be presented to the Minister by 31 May 2012, will set out findings and conclusions in relation to the following terms of reference:

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.

The review team considered that it was essential that families of those babies affected by the pseudomonas incidents should be provided with an early opportunity to meet with the team and meetings with eight families have taken place.

8.2 First Term of Reference

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

In the period from 1 November 2011 to 31 January 2012, outbreaks of *Pseudomonas aeruginosa* occurred in the intensive care rooms of two neonatal units in Northern Ireland, at Altnagelvin Hospital and Royal Jubilee Maternity Service (RJMS). A cluster of cases was linked to Craigavon Area Hospital Neonatal Unit. A baby was colonised who was born and cared for in Antrim Area Hospital Neonatal Unit. No cases of colonisation or infection were found linked to the Ulster Hospital Neonatal Unit.

8.2.1 Analysis of strains found in babies

Analysis of typing of strains of *Pseudomonas aeruginosa* linked to the outbreak has been complex as several different strains have been linked to the outbreak. This work is ongoing. The findings to date indicate that the infection or colonisation of babies in each of the four neonatal units was associated with different strains of *Pseudomonas aeruginosa*.

In Altnagelvin three babies became infected in early December 2012. Two had a single strain and one had a different strain.

In RJMS four babies became infected and 11 were colonised with a single strain of *Pseudomonas aeruginosa.* One of the colonised infants subsequently became infected following transfer to another neonatal unit. The earliest identified sample linked to this strain was on 15 November 2011 and the latest on 23 January 2012.

In Craigavon, three babies were found to be colonised with a single strain of *Pseudomonas aeruginosa* from samples taken on 20 and 24 January 2012. A baby who

had been transferred from Craigavon to RJMS on 9 January and who became infected and died in RJMS also had this strain.

In Antrim, a baby who was colonised had a separate, unrelated strain.

The Review Team has concluded that incidents relating to *Pseudomonas aeruginosa* infection and/or colonisation of babies in four neonatal units in Northern Ireland were each caused by different strains of the organism, which means they were separate outbreaks/clusters.

8.2.2 Links to strains found in water, taps and sinks

During the period when the incidents linked to *Pseudomonas aeruginosa* occurred, a large number of environmental and water samples were taken. Samples were collected in different ways in the early stages until standardised techniques were put in place. Analysis of samples for strain typing is still ongoing and a detailed analysis of taps is taking place. Nevertheless, the review team considers that the information available to date points to emerging findings and conclusions.

All five neonatal units in Northern Ireland had evidence of *Pseudomonas aeruginosa* contamination in some of the water, sink or tap samples which were tested.

In Altnagelvin Hospital, each of the two strains which led to the infection of babies was found in one of the taps or sinks in the ICU room. One of these strains was found at the time the babies were infected. The other strain was found on a swab taken on 12 January 2011 from a tap which had been previously negative. One infrequently used tap in a part of the room which was rarely used to care for babies was found to be contaminated with pseudomonas.

In RJMS, the strain which has been associated with five cases of infections and 10 colonised babies was detected in samples from four out of six taps in the main NICU room and also from a tap in SCBU.

In Craigavon Area Hospital, a direct link has not been established between the strain linked to babies and strains tested through water sampling.

In Antrim Area Hospital, the strain in a colonised baby was different to those found in water samples.

These findings indicate strong links between the cases of infection and colonisation at Altnagelvin and RJMS and the tap water in the units. In Craigavon and Antrim, links have not been established, but cannot be ruled out at this stage.

The review team has been advised that the taps and sinks in RJMS and Craigavon neonatal units had been recently replaced, prior to the incidents. The taps and sinks in Altnagelvin neonatal unit had been in used since the unit opened in February 2009. A refurbishment of RJMS had taken place in August and September 2011 during which new taps and sinks had been installed. Craigavon Neonatal Unit had a significant refurbishment, which was completed in March 2011. This included the fitting of new sensor taps and sinks in the refurbished areas.

Sensor taps, which do not require the operator to touch the tap, had been installed in all three units. Concerns about links between sensor taps and pseudomonas infection have previously been raised as set out in Section 5. The taps removed following the incidents have been sent for analysis and the review team will consider the findings when preparing the final report of the review.

During the Altnagelvin outbreak, the initial samples from taps were taken using swabs. Following the declaration of the outbreak in RJMS, regional guidance was issued on instituting water sampling and as to how water samples should be taken in a standardised manner. Trusts have advised that the presentation of test results can be different depending on the laboratory used. Some laboratories provide greater degrees of detail in relation to the level of any pseudomonas bacteria found which is helpful to assess levels of contamination.

Prior to the incidents, routine sampling of water was not carried out in relation to pseudomonas in augmented care settings across Northern Ireland. This has been introduced for neonatal care units following introduction of interim guidance issued by DHSSPS on 9 February 2012 in HSS (MD) 6/2012.

Further guidance was published on 30 March 2012 by the Department of Health (DoH) in England. The review team recommends that the current arrangements in Northern Ireland are continued pending early consideration of the DoH guidance. This will be relevant to all augmented care settings.

The review team has concluded that 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 is 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. Installation of sensor taps in Altnagelvin, Royal Jubilee Maternity and Craigavon hospitals prior to the outbreaks may have contributed to creating an environment for pseudomonas to become established.

8.2.3 Methods of spread of infection

The review team has sought evidence as to potential routes of transmission, through which babies could have been colonised or infected with pseudomonas from contaminated taps or sinks in the units.

The review team found that in the five neonatal units in Northern Ireland it was normal practice to use tap water for nappy changes. This has also been common practice in other parts of the United Kingdom. In units using tap water, a small container of tap water was taken from hand washing stations. The review team consider that this was a likely route for transmission of pseudomonas from taps to babies.

The review team has been advised that in the RJMS Neonatal Unit, a further potential route of transmission was through the method by which expressed breast milk was defrosted. Fresh breast milk can be frozen for up to three months. It can be defrosted in a refrigerator over several hours or more rapidly under a flow of tepid water from a tap or by standing in a container of tepid water in line with extant guidance. Tap water in neonatal units was being used for this purpose and this may have led to transmission.

Contamination of the skin of a baby may lead to subsequent colonisation but not necessarily to infection. The review team has found that the babies who developed infection in the neonatal units required many invasive procedures such as putting in intravenous lines and intubation for ventilation. There is a high risk that such procedures can lead to invasive infection when a baby has been colonised or the skin contaminated with pseudomonas.

The review team has concluded that 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 to defrost breast milk previously frozen for storage may also have contributed in Royal Jubilee Maternity Service. Device related invasive procedures are likely to have contributed to the development of infection when babies had been colonised with the organism on their skin.

8.2.4 Other Factors Which May Have Contributed to the Pattern of Cases:

8.2.4.1 Fabric and design of units

Members of the review team have undertaken a series of visits to each neonatal unit. All have reported that they observed a marked difference in the fabric of the estate between the RJMS Neonatal Unit and the other units.

Neonatal Units at Altnagelvin and Ulster hospitals are located in new purpose-built facilities, opened within the last five years. They are spacious, well designed and have appropriate rooms to enable segregation of infected babies. Craigavon Neonatal Unit, although located in an older building, underwent a very significant refurbishment recently, which created a spacious and bright ICU environment with facilities for segregating infants.

Antrim Neonatal Unit is about 20 years old with separate rooms. The review team considered that the unit was generally well designed, but would benefit from the creation of additional space for the ICU room to facilitate staff movement and the use of equipment. Plans are currently in place to increase the footprint of the ICU room during 2012/2013.

The Neonatal Unit at RJMS is located in a building which opened in 1933. A planned move to a new unit is to take place in around four years' time. The main room in which the Regional Neonatal Intensive Care Unit is located is a single room with 12 cots. The unit does not have appropriate facilities for isolation, and limited space for staff to clean equipment and incubators. There is limited space for circulation within the ICU room. The distance between cots and the sluice room is likely to have contributed to the use of hand washing sinks to dispose of water after cleaning babies, and thus potentially to the spread of contamination between taps. The roof of the building leaks and the water pipework to the building is old.

The Review Team has concluded that the design of the Royal Jubilee Maternity Unit does not facilitate staff in carrying out good principles of infection prevention and control. It is recommended that the move to a new unit is expedited as quickly as possible. In the interim, steps should be taken to improve space around cots, and to create better facilities for segregation of babies with infections and for cleaning equipment and incubators.

8.2.4.2 Cleaning practices

Specific standards on cleaning methods, or on the risk assessment of functional areas and elements to determine the frequencies at which areas should be cleaned and audited, are implemented in each trust using the DHSSPS *Cleanliness Matters Toolkit* and the NPSA *National Specifications for Cleanliness in the NHS*. The review team noted that there were slight variations in cleaning practices and the frequency of cleaning between units.

All units used the above guidance and the British Institute of Cleaning Sciences BICS (Revised September 2011) method for sink cleaning or an adaption of this procedure. This procedure instructs staff to clean sinks from bottom, cleaning the taps last.

The new guidance issued from the CMO on 28 January 2012 stated that taps in neonatal units should be cleaned first starting at the base upwards from back to front working up to the nozzle and water outlet. The review team recommends that the interim guidance is reviewed to ensure that there is consistency of practice across all clinical areas.

Variations were also observed in the cleaning of incubators and where they were cleaned. In four of the units cleaning of incubators was undertaken by nursing staff. In RJMS the incubators were cleaned by staff from Patient Client Support Services (PCSS). A neonatal technician was responsible for cleaning the humidifier tray and medical attachments and signing off prior to reuse. The neonatal unit in the Southern Trust is the only unit to have a separate room for the decontamination of incubators. In the RJMS incubators are cleaned in the corridor and in other units the dirty utility room is used.

The Review Team has concluded that staff were carrying out cleaning procedures in line with recognised guidelines. It is recommended that the interim guidance dated 28 January 2012 on cleaning sinks be reviewed to provide further clarity in this matter.

The Review Team also concluded that there should be a regional approach and guidance on the cleaning of incubators and other specialist equipment for neonatal care.

8.2.4.3 Hand hygiene and use of personnel protective equipment

All units carried out self-validation hand hygiene audits and were able to produce a record of hand hygiene audit results and frequency. All units advised the review team that Independent Hand Hygiene Audits were carried out. However the review team has noted that there was variation in the methods and frequency of approach and in relation to action planning to address non-compliance issues.

The review team has been advised by two trusts (Belfast and South Eastern) that alcohol gel was routinely used after hand washing in neonatal units prior to the pseudomonas incidents. The CMO interim guidance issued on 28 January 2012 in **Circular HSS (MD) 4/2012** stated that the HPA had advised that a hand rub conforming to BS EN 1500 (*Chemical disinfectants and antiseptics. Hygienic hand rub. Test method and requirements)* should be used after washing and this would be sufficient to eliminate the risk of infection.

The review team noted that disposable plastic aprons were not worn on all occasions to protect uniforms and clothes from water splashes when undertaking wet work such as in RJMS when cleaning the incubators. They were also not always worn when undertaking invasive procedures where there is direct contact or a risk of contamination from blood or body fluids.

The Review Team concluded that independent validation of hand hygiene audits should be carried out on a regular and ongoing basis, supported by robust action plans where issues of non-compliance are identified. The team also recommends the appropriate use of PPE.

8.2.4.4 Occupancy rates

The review team has been provided by trusts with information about occupancy rates in neonatal units across Northern Ireland for the period from September 2010 to January 2012 (Section 4.4). These figures indicate that there were high levels of occupancy for Intensive Care (Level 1) across Northern Ireland for the period from November 2011 to January 2012 when the pseudomonas incidents occurred. In Altnagelvin Hospital this led to cot spaces in the ICU room being used which were not usually opened.

The Review Team concluded that during the period of the outbreaks the occupancy rates for intensive neonatal care were high which increased the pressures on the neonatal care system at that time.

8.2.4.5 The vulnerability of the babies who became infected

Nine babies became infected with *Pseudomonas aeruginosa* during the period from 1 November 2011 to 31 January 2012, five of whom died. Information provided to the review team has indicated how vulnerable these babies were to the risk of infection. Five of the babies were born at less than 26 weeks gestation and two others between 27 and 29 weeks. Babies of this age have very fragile skin and their immune systems are not fully developed. They have limited immunity transferred from their mother across the placenta.

All the babies had significant other problems and they received many invasive procedures including insertion of peripheral and central lines and intubation. All the babies had required Level 1 Neonatal Care which is the highest category of provision required.

The review team has concluded that the vulnerability of the babies predisposed them to a very high risk of infection. They consider that, in developing guidance to reduce risk of infection from pseudomonas in augmented care settings, additional safeguards should be considered for intensive and high dependency neonatal care including sterile water only to be used for washing.

8.2.5 Summary of Conclusions in Relation to the First Term of Reference

The RQIA review team has concluded that incidents relating to infection or colonisation with *Pseudomonas aeruginosa* which occurred between November 2011 and January 2012 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 is 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. Installation of sensor taps in Altnagelvin Royal Jubilee Maternity and Craigavon hospitals prior to the incidents may have contributed to creating an environment for pseudomonas to become established.

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. 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. It is 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.

Cleaning practices for taps and sinks were in line with recommended practice before the outbreaks. However, the previously recommended practice is significantly different from the practice recommended in interim guidance for neonatal units issued after the outbreaks were declared. The review team recommends that guidance on cleaning sinks should be standardised across all clinical areas.

Two trusts advised that it was routine practice to use alcohol gels after hand washing in neonatal units before the incidents. This was introduced to all trusts when regional guidance was issued after the outbreaks were declared. The review team recommends 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 recommends that this is continued until there is an opportunity for Northern Ireland to fully consider the new guidance issued on 30 March 2012 by the Department of Health (England).[14]

[14] Water Sources and potential *Pseudomonas aeruginosa* Infection of Taps and Water Systems: Advice for augmented care units: Department of Health (March 2012).

8.3 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 has been provided with extensive documentation about the management of the occurrences of pseudomonas infection and colonisation. There is clear evidence that staff in all trusts acted to reduce risks of spread of infection and to investigate why the incidents had occurred. The review team has 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.

8.3.1 Collation and sharing of information about cases

Critical decisions about the identification and management of incidents related to infectious diseases require relevant information to be available at the appropriate time. The review team has found that this was not always the case during the management of the incidents of pseudomonas.

Case finding carried out by the PHA has identified earlier cases of colonisation, which were not known about at the time when decisions on whether to call an outbreak in RJMS were being taken. Subsequently, these were linked to the outbreak strain there. Information on positive results was not routinely fed back to previous units in which babies were cared for, which could trigger important action if there was a possible link between cases. Information was sometimes provided on an ad hoc basis about events in different units.

Information on bacterial infections of the blood is collected centrally by PHA through the Communicable Disease Surveillance System (CoSURV). However, there is not a routine surveillance system for pseudomonas. Systems are in place for MRSA and *Clostridium difficile.* The review team recommends that appropriate surveillance arrangements should be established for *Pseudomonas aeruginosa* for augmented care settings including neonatal care.

One baby was transferred between Altnagelvin and RJMS who had a known pseudomonas infection at the time of transfer. In this case, there was evidence of good transfer of clinical information and, when a blood culture was found positive at Altnagelvin after the baby had left, this information was promptly passed on to RJMS.

The review team has concluded that the lack of an agreed system for the surveillance of pseudomonas colonisation and infection led to delays in sharing of information between trusts in some cases which may have impacted on subsequent decision making.

8.3.2 Response to a case of *Pseudomonas aeruginosa* in a neonatal unit

The review team found that a single case of colonisation or infection by *Pseudomonas aeruginosa* in a baby was responded to clinically for the baby, but did not result in an investigation as to a possible source of infection. This is in keeping with normal practice for infection control for most organisms, where a source will not be sought unless at least two cases are involved. For particular high-risk organisms such as meningitis in a child, a single case would trigger immediate action.

The findings of the review team in these incidents suggest that identification of a case of pseudomonas in a neonatal unit indicates that the baby may have been exposed to an environmental water source of infection. This could have occurred while in that unit or in another unit where the baby was previously cared for since birth. Early pre-term babies are extremely vulnerable to infection with pseudomonas infection.

The findings of the review team also indicate that if water testing of taps and sinks close to the baby had taken place in units when a first baby was found to have been colonised or infected, taps contaminated with *Pseudomonas aeruginosa* might have been identified earlier in both Altnagelvin and RJMS neonatal units.

The review team has concluded that the response to the identification of the initial case of *Pseudomonas aeruginosa* in each unit was in keeping with normal practice. In the light of the findings of this review, it is 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 which had been occupied by that baby since birth.

8.3.3 Process for declaring an outbreak

The review team has considered the processes with which outbreaks of *Pseudomonas aeruginosa* were declared at Altnagelvin and RJMS neonatal units.

At Altnagelvin, an outbreak was declared at a meeting of an incident team on 12 December 2011 when there had been three confirmed cases of *Pseudomonas aeruginosa* in the previous 14 days. Positive sample results were confirmed on 28 November, 8 December and 12 December 2011. No information on strain typing was available at that time. In Altnagelvin, enhanced infection control measures were put in place on the day the outbreak was declared. This included environmental sampling, including swabbing of taps, but not testing of water. As part of the enhanced infection control measures, the infection control team recognised the potential risk associated with water sources and introduced the use of sterile water instead of tap water which was being used during nappy changes.
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At RJMS there were two known cases of *Pseudomonas aeruginosa* in the unit in December 2011 with the possibility that spread had occurred between the babies. Infection control arrangements were enhanced including co-locating the two babies to reduce the risk of spread of infection to others. A decision was taken to seek typing as quickly as possible, rather than declare an outbreak. Typing results confirmed these were different strains. Subsequently, when another case was confirmed positive on 7 January 2012, infection control arrangements were put in place and typing was requested to determine whether there was a link to one of the earlier cases.

On 15 January 2012, results were confirmed positive for *Pseudomonas aeruginosa* from a baby who had died the previous day.

On 16 January 2012, the typing results were provided and confirmed that two babies had had the same strain. An incident team meeting was held on the following day. Environmental sampling was then carried out and a programme of control measures was put in place.

The findings indicate differences in approach to the declaration of outbreaks across the units. Altnagelvin declared an outbreak following three cases without typing results. Belfast Trust requested typing after two cases to determine whether they were related and put enhanced infection control measures in place. It later declared an outbreak following consideration that three cases were potentially related, of which two had been found to have the same strain.

The review team has concluded that there was no agreed approach across neonatal units in place for the declaration of outbreaks. Environmental sampling including testing of water for pseudomonas was not carried out prior to the confirmation of the outbreaks in Altnagelvin or RJMS.

8.3.4 Arrangements to carry out typing of *Pseudomonas aeruginosa*

At present, typing of *Pseudomonas aeruginosa* is carried out in the HPA Reference Laboratory in England for samples from Northern Ireland. The Reference Laboratory has analysed a large number of samples from babies and the environment in relation to the incidents subject to this review. These results have been fundamental in understanding the events which occurred.

The process of sending samples to England does take time and may have led to delays in recognising the pattern of the incidents which occurred. The review team has concluded that the establishment of arrangements for typing *Pseudomonas aeruginosa* in Northern Ireland would facilitate the earlier investigation of cases of infection and the earlier identification of related cases.

The review team has concluded that the establishment of arrangements for typing of *Pseudomonas aeruginosa* in Northern Ireland would reduce the risk of delays in identification of related incidents of infection.

8.3.5 Neonatal network arrangements in Northern Ireland

The review team has 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.

A position paper on Specialist Neonatal Services in Northern Ireland in May 2006 stated that babies born before 28 weeks gestation and weighing less than 1,000 grams should receive their initial care in the regional unit (see Section 4.3.2). The review team has been advised that this is increasingly not being achieved. The three infected babies being cared for in Altnagelvin Neonatal Unit during the outbreak were all under 26 weeks.

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 considers that arrangements for the provision of neonatal care would be greatly strengthened by the establishment of a formal 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.

8.3.6 Summary of Conclusions in Relation to the Second Term of Reference

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

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, taps and sinks should be tested in rooms which had been occupied by that baby since birth.

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. It is recommended that an agreed approach is established across all trusts.

At present, typing of strains of *Pseudomonas aeruginosa* is carried out in England. It is 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 is 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. 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.

9. Recommendations

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.[15]

2 Tap water should not be used in maternity and neonatal units during the process of defrosting frozen breast milk.

3 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.

4 The presentation of test results of water samples should be standardised across the laboratories which undertake this for HSC organisations.

5 The review team recommends that guidance on cleaning sinks should be reviewed so that practice is standardised across all clinical areas.

6 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.

8 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.

10 Surveillance arrangements should be established for *Pseudomonas aeruginosa* for augmented care settings including neonatal care.

11 All relevant organisations should work to an agreed regional protocol for the declaration of outbreaks.

12 Arrangements for the typing of strains of *Pseudomonas aeruginosa* should be established in Northern Ireland.

13 A regional neonatal network should be formally established in Northern Ireland.

[15] Water Sources and potential *Pseudomonas aeruginosa* Infection of Taps and Water Systems: Advice for augmented care units: Department of Health (March 2012).

14 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.

15 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.

10. Next Steps

This report presents the interim findings and conclusions of the independent review of the incidents of pseudomonas infection and colonisation in neonatal units in Northern Ireland.

The purpose of the report is to identify any immediate actions which should be taken forward prior to the completion of the final report of the review. This report makes 15 recommendations on the basis of the evidence which has been considered to date.

It is important to emphasise that since 30 January 2012 there have been no further incidents or outbreaks in neonatal units across Northern Ireland, which strongly indicates that the control measures put in place were successful.

During the second phase of the review, the review team will examine governance arrangements and the effectiveness of communication in relation to the pseudomonas incidents. The actions taken in response to relevant circulars and advices from DHSSPS will also be reviewed. Further consideration will be given to how organisations responded to the incidents as they unfolded. Staffing of units will also be considered. A number of other issues have emerged during phase one which require further clarification and these will be considered during phase two of the review.

In parallel with the work of the independent review team, a number of significant pieces of work are being taken forward at national and regional level. During the second phase of this review, the review team will engage further with the groups carrying out this work to ensure that emerging findings inform the final review report.

During the second phase of the review, a major focus will be on the experience of families. The review team are very grateful to those families who have met with the team during the first phase. The information they have provided has been invaluable. During the next phase the team would welcome the opportunity to talk to other families affected by the incidents should they wish to avail of this request.

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
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
PICU	Paediatric Intensive Care Unit
PPE	Personal Protective Equipment
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

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