A REVIEW OF ABERTAWE BRO MORGANNWG UNIVERSITY HEALTH BOARD'S (ABMU) RESPONSE TO THE ESBL *E.COLI* CROSS INFECTION IN THE MATERNITY/NEONATAL UNIT AT SINGLETON HOSPITAL IN NOVEMBER 2011

March 2014

Contents

Executive Summary

In November 2011, an Extended Spectrum Beta-Lactamase[1] producing *Escherichia coli* (ESBL *E.coli*)[2] transmission event occurred in the Neonatal Unit (NNU) at Singleton Hospital part of Abertawe Bro Morgannwg University Health Board (ABMU HB). The Health Board asked Healthcare Inspectorate Wales (HIW) to undertake an independent review of its management of and response to the incident to ensure that any lessons to be learnt were identified and appropriately acted upon. The remit did not include the clinical management of cases.

The incident involved a mother (Mother A) and her twins (Baby A1 and A2) and a third baby (Baby B1). All three babies were premature and were delivered by caesarean section on 31 October 2011. All three babies required neonatal intensive care at birth.

Prior to giving birth, Mother A was colonised with ESBL *E.coli* and subsequently after delivery showed signs of infection. Baby A1 developed an ESBL *E.coli* bacteraemia and later other serious medical complications. Baby A1 subsequently died on 8 November (Day 8 after birth). Baby B1, who was being cared for in an adjacent incubator cot to Baby A1 on the NNU had acidosis[3] after birth. There was a period of improvement, however, later on 3 November Baby B1 showed signs of sepsis[4] and deteriorated rapidly. Sadly, Baby B1 died on 4 November (Day 4 after birth). Blood cultures taken immediately after Baby B1's death highlighted that the sepsis was due to ESBL *E.coli*. Baby A2 was colonised with ESBL *E.coli* but remained well and was discharged home on November 17 (Day 17 after birth).

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[1] See Annex B

[2] See Annex A

[3] Acidosis is an increased acidity in the blood and other body tissue. It is said to occur when arterial pH falls below 7.35.

[4] Sepsis is a potentially deadly medical condition characterised by a whole-body inflammatory state caused by a severe infection.

Molecular techniques[5] found all four ESBL *E.coli* strains[6] (strains from Mother A, Baby A1, Baby A2 and Baby B1) to be the same by the current molecular techniques used at the reference laboratory at that time.

In an augmented care setting such as a NNU, failures to maintain good hand hygiene, best practice in managing devices or a break down in infection prevention and control practice may result in transmission of pathogens[7] to other neonates and may result in a subsequent outbreak.

During the lead up to the events of November 2011, the NNU unit was busy and operating beyond the contracted cot allocation. There were two sick babies adjacent to each other; this was a significant factor in this event. It transpired that one was colonised with ESBL *E.coli.* A transmission event occurred between 9pm on 31 October 2011 and 3 November 2011. The practice of putting two babies requiring intensive care next to each other especially when the distance between cots was not optimal and when in hindsight one was colonised with an Alert organism[8], needs to be reconsidered. In future, if this were to be allowed for operational reasons, a strict one to one nursing policy must be put in place for both babies.

On the suspicion of one baby being colonised and the other displaying signs of sepsis, treatment on the second baby (B1) was changed and the unit closed to admissions on the night of 3 November 2011. This was a precautionary and necessary decision.

While these outbreaks are rare, over the last decade, infections caused by *Escherichia coli* possessing Extended Spectrum Beta-Lactamase have been increasing reported. From time to time they lead to increased morbidity and

[5] Molecular Techniques: Detailed examination of the organism to characterise it or to detect similarities or differences between the same strains of organisms.

[6] Molecular analysis by pulse field gel electrophoresis (PFGE) demonstrated a common strain identified as SWANPES-1. All four ESBL E coli strains (strains from Mother A, Baby A1, Baby A2 and Baby B1) were designated SWANPES-1 by the reference laboratory.

[7] A Pathogen or infectious agent is a microorganism, such as a virus, bacterium, prion or fungus that causes disease in its host.

[8] Alert Organisms are identified in the microbiology laboratory and include organisms such as MRSA and other antibiotic resistant organisms

occasionally tragic mortality. This is what occurred in the neonatal unit at Singleton in November 2011.

While the exact cause of the transmission event and hence the outbreak cannot be determined it was most likely caused by a failure in infection prevention control within the NNU. However, as a consequence of the actions taken by staff on the NNU, the infection prevention control team, the outbreak management team and the ABMU Health Board, the outbreak was limited to just the one transmission event.

Not all outbreaks are the same and the management procedures and process have to be modified according to the control measures required. However, on the whole, ABMU HB followed its outbreak management policy entitled *"Infection Outbreak/Incident Management on Hospital Premises"* produced by the Department of Infection Prevention & Control and issued in January 2011.

The subsequent internal reviews undertaken by ABMUHB following the incident identified certain areas where improvements were required. These included:

- inadequate hand wash basin provision
- lapses in hand hygiene practice for some disciplines, in particular medical staff
- the need to increase the spacing between neonatal cots in the NNU
- an increase in the number of level 1 and 2 cots to address increased demand and levels of acuity
- cleaning and decontamination responsibilities not consistently formulised, particularly in relation to shared equipment on the NNU
- concerns noted around the general maintenance of flooring and cupboards

Although an outbreak of this nature can be complex, if a similar outbreak were to occur in the future the Health Board's immediate response must be more rapid, more rehearsed, refined and operated with precision.

Further, the temporary transfer/relocation of the NNU to another area of the hospital has allowed AMBU HB time to address some of the improvements required for the operation of a modern neonatal service.

Additional infection prevention control training was carried out after the event and will help reinforce key practices.

This incident has wider implications than just ABMU HB and NHS Wales must ensure that the conditions that existed in the NNU at the time of the outbreak are not present elsewhere in Wales. Also it is important that the proposed reconfiguration of neonatal services across South Wales takes into account the surveillance of infection and the adequate provision for infection prevention and control and sustained staff training and education. Neonatal Services must be adequately resourced and matched with demand and the level of care required. Provision must be made for adequate facilities for storage of equipment, clean equipment and a clean and serviceable environment. Best practice in all areas must be delivered at all times.

We believe that the outbreak meetings, the root cause analysis exercise, staff interviews, and various reports and evaluations of how the outbreak was managed, undertaken by the Health Board, has allowed those responsible and accountable to learn from this event and take action.

Recommendations

In relation to the Health Board:

Recommendation 1

The NNU with the help of the Infection Control Team and the medical microbiologists should devise an early warning system to alert the neonatologists and Neonatal Unit staff of alert organisms likely to lead to a transmission incident/outbreak.

Recommendation 2

The Health Board should develop an appropriate system to monitor unit activity and staffing and provide an early provision of adequate resources when activity is not matched with safe levels of staffing resources to maintain patient safety[9].

Recommendation 3

The Health Board should reinforce its continuing infection prevention and control training programme for all staff. This should be mandatory and monitored – non compliance should lead to a failure in appraisal. Visual monitoring and challenge should become the norm in regards to infection prevention and control[10].

Recommendation 4

It is recognised that staff will be reluctant to transfer sick neonates to other institutions during an incident/outbreak however; the Health Board and the local Neonatal Network should devise an action plan, similar to a major incident plan, for the safe transfer or local management of neonates and develop the criteria for this to occur should the situation require.

[9] In line with 'Chief Nursing Officer Guiding Principles for Nurse Staffing Levels Wales April 2012'

[10] The principles outlined in the NICE/HPA Quality Statements (Nov 2011) should be adopted by the Health Board and relevant sections should be adopted. See: http://www.nice.org.uk/guidance/PH36

Recommendation 5

The Health Board should ensure that there is provision for easily accessible hand washing stations in compliance with national standards[11].

Recommendation 6

The Health Board should review its visitor policy. This should take into account children, visitors, requirements for parents and rules around NNU etiquette. Similar guidance for NNU staff working on the unit and visiting should be developed.

Recommendation 7

As part of the strategy to prevent future outbreaks and although this was not a water system related incident, the Health Board should comply with the Welsh Government statements on Water Supply and management[12].

In relation to the Neonatal Network:

Recommendation 8

The Neonatal Network should look at this incident, extract the lessons learnt and disseminate this learning to all NNU's in Wales to ensure that the risk of such a future event is minimized – staff at all levels and grades should be involved.

[11] See: http://www.bapm.org/publications/documents/guidelines/DesigningNNU_May2004b.pdf

[12] See: http://wales.gov.uk/topics/health/ocmo/publications/cmo/item/water/?lang=en

See: http://wales.gov.uk/topics/health/ocmo/publications/cmo/item/contamination/?lang=en

Recommendation 9

The Neonatal Network should look at other units within its geographical area and ensure that units have adequate space and staffing levels. Concerns in regards to this should be communicated to the relevant Health Boards highlighting the risks and request they urgently correct any deficiencies in these areas.

Recommendation 10

The Neonatal Network should review its arrangements to ensure that when outbreaks of this nature occur, the Network is able to absorb the closure of a NNU, taking into consideration that this will increase pressure on the Network itself.

Recommendation 11

As part of the strategy to prevent future outbreaks and although this was not a water system related incident , the NNUs within the Neonatal Network should comply with the Welsh Government statements on Water Supply and management[13].

In relation to Welsh Government and Public Health Wales:

Recommendation 12

Public Health Wales and Welsh Government should consider undertaking a review of the common causes of NNU outbreaks. The outcome of this review and the learning points for best practice should be disseminated to all Health Boards. The Health Boards should adopt the learning. After a suitable period, an audit should be completed to provide assurance of best practice/compliance.

[13] See: http://wales.gov.uk/topics/health/ocmo/publications/cmo/item/water/?lang=en

See: http://wales.gov.uk/topics/health/ocmo/publications/cmo/item/contamination/?lang=en

Recommendation 13

Welsh Government should review the '*All Wales Inter Hospital Transfer Documentation*' to ensure that this documentation sufficiently captures any information that may refer to treatment received abroad.

Chapter 1: Introduction and Background

Introduction

1. In November 2011, Healthcare Inspectorate Wales (HIW) was notified of an Extended-Spectrum–Beta-Lactamases (ESBL) *E.coli* cross infection in the Neonatal unit at Singleton Hospital, part of Abertawe Bro Morgannwg University Health Board (ABMU HB). ESBL *E.coli* were identified in 3 premature babies and 1 postnatal woman. Sadly one of the premature babies passed away on 4 November 2011 and a further baby died on 8 November 2011.

2. The Health Board established its own internal investigation into the incident. A Root Cause Analysis was carried out, staff were interviewed and as part of the ongoing investigation several meetings chaired by senior Health Board staff were conducted. The Health Board requested HIW to undertake an independent review of its *management* of and response to the incident to ensure that any lessons to be learnt were identified and appropriately acted upon. The remit did not include the clinical management of cases.

Terms of Reference

3. HIW undertook a focused review to ensure that the Health Board:

- took all reasonable steps to identify and address the cause(s) of the cross infection.
- managed the matter in an effective and timely manner that avoided further incidents of cross-infection.
- has learnt from the incidents and put in place arrangements that will minimise future cross infection.

4. A Consultant Medical Microbiologist was appointed to the review team and a range of primary evidence was examined and a visit undertaken to the Maternity and Neonatal Ward at Singleton Hospital.

Neonatal Unit (NNU)

5. Over the last fifty years standards of neonatal care have been founded on basic science, clinical research, clinical experience and observation.

6. The British Association of Perinatal Medicine Service Standards (BAPM)[14] states that Hospitals providing neonatal care, should provide care through high quality neonatal services within a network comprising of three types of units:

- Special Care Units (SCU): These provide special care for their own local population. They also provide, by agreement with their neonatal network, some high dependency services.
- Local Neonatal Units (LNU): These provide special care and high dependency care and a restricted volume of intensive care (as agreed locally) and would expect to transfer babies who require complex or longer-term intensive care to a Neonatal Unit.
- Neonatal Unit (NNU): These are larger intensive care units that provide the whole range of medical (and sometimes surgical) neonatal care for their local population and additional care for babies and their families referred from the neonatal network in which they are based, and also from other networks when necessary to deal with peaks of demand or requests for specialist

[14] http://www.bapm.org/publications/documents/guidelines/BAPM_Standards_Final_Aug2010.pdf

care not available elsewhere. Many will be sited within perinatal centres that are able to offer similarly complex obstetric care. These units will also require close working arrangements with all of the relevant paediatric sub-specialties.

Neonatal units in Wales

7. There are thirteen Neonatal Units (NNU) in Wales. Each year, around 4000 neonates are admitted to these units[15].

8. The NNU for Abertawe Bro Morgannwg University Health Board (ABMU) is currently situated on two sites, offering level 3 (intensive, high dependency and special care) at Singleton Hospital, Swansea and level 2 care (high dependency and special care) at Princess of Wales hospital, Bridgend. The NNU is part of the South West Wales mini-neonatal services network. The network comprises Bronglais Hospital, Withybush Hospital, West Wales General Hospital, Singleton Hospital and Princess of Wales Hospital.

9. The ABMU Health Board is responsible for approximately 6700 births per year which take place over a variety of birth care settings, including a level 3 obstetric unit at Singleton, Swansea, a District General Hospital at the Princess of Wales in Bridgend, a stand alone Birth Centre at Neath Port Talbot and a successful home birth service.

10. The NNU at Singleton is a level 3 Neonatal Unit. The Unit was funded for 5 Level 1 Cots, 4 Level 2 Cots and 15 special care cots (see description at paragraph 12).

11. Annually the ABMU NNU cares for and provides intensive support to 400-500 neonates. In 2011 there were approximately 367 admissions into the NNU in Singleton.

[15] http://www.senedd.assemblywales.org/documents/s9839/Neonatal%20Care%20-%20Report%20-%20September%202012.pdf

12. Adequate levels of staffing are required to provide intensive care. The standards[16] for staffing on neonatal units are:

- Level 1 (Intensive Care (IT)) nursing ratio 1 neonatal nurse to 1 baby
- Level 2 (High Dependency (HD)) nursing ratio1 neonatal nurse to 2 babies
- Level 3 (Special Care (SCBU)) nursing ratio 1 neonatal nurse to 4 babies

13. The staffing establishment of the Singleton NNU at the time of this outbreak consisted of 70.57 Whole Time Equivalent (WTE).

14. At the time of the incident, within the NNU there were 5 funded ITU cots, 4 funded HDU and 15 SCBU. On 1 November 4 ITU cots, 1 HDU cot and 8 SCBU cots were occupied. However, ITU occupancy rose from 4 to 8 on 6 November, with HDU occupancy also increasing to 3. This resulted in 11 babies requiring HDU or ITU care, there were 2 shifts during this period when staffing levels breeched recommended levels given the nursing ratio's required due to the acuity of the babies being cared for (see paragraph 12), by 1 nurse[17].

15. On occasions when activity exceeds capacity, the ABMU NNU at Singleton is supported by the South Wales NNU network.

Outbreaks in Neonatal Units

16. Although outbreaks in NNU's are not common, they do occur from time to time.

[16] http://www.bapm.org/publications/documents/guidelines/hosp_standards.pdf

[17] The period referred to was 5th and 6th November 2011. The defined level according to acuity was 10 nurses, but the number of nurses was 9.

17. Many outbreaks reported in NNU's have been associated with *Escherichia coli* or other similar Gram negative organisms[18]. Some have been caused by pathogens that have the capability of producing ESBL enzymes. Organisms such as MRSA and MSSA[19] have also been reported to have caused outbreaks.

18. When outbreaks of this nature occur, the responsible staff on the NNU, after an appropriate risk assessment, must consider the closure of the unit to admission and avoid transfers to other NNUs. This may lead to a disruption in service delivery. Closures of this type impact on maternity services and some neonates requiring specialist neonatal care may need to be transferred to another unit in the network in a safe way.

The Singleton NNU ESBL *E.coli* Outbreak: November 2011

19. In November 2011, an ESBL producing *E.coli* outbreak occurred in the Singleton Hospital NNU. Sadly, two pre-term babies (A1 and B1) died from infections caused by this pathogen. The organism was detected in blood cultures from both babies at different times. In one case (B1) the baby died prior to the availability of the microbiology result. The colonisation of Babies A1 and A2 was likely to have been by vertical transmission from their Mother. The infection in Baby B1 appeared to be by horizontal transmission.

20. The NNU was closed to admissions on 3 November 2011 at 22:00 hrs by the duty Neonatologist when the Health Board suspected an outbreak and prior to the microbiological confirmation of the second case.

21. Infection prevention and control measures were instituted and a screening programme was commenced. No further transmission events

[18] A Gram stain is a technique used to differentiate bacteria using a colour stain. Gram negative bacteria stain pink, *E.coli* and other similar bacteria stain pink. They are generally carried in the bowel of a person.

[19] MSSA - Methicillin sensitive Staphylococcus aureus

were identified and the outbreak was reported to the ABMUHB's Board, Public Health Wales and the Welsh Government.

22. The decision to screen for infection is dependent on infection control advice when an alert organism is reported from routine samples or clinical samples sent from neonates. Occasionally, as in this instance once an alert organism is detected a decision may be made to screen the neonates on the rest of the unit to determine the extent of spread. Apart from the ESBL *E.coli* strains isolated from Mother A, Baby A1, Baby A2 and Baby B1, in this instance, the screening revealed a further colonised mother on 14 November 2011, and two other babies were also found to be colonised on 25 and 26 November 2011. These were also ESBL *E.coli* but the strains were not related to the strains that affected Baby A1, A2 and B1. Sophisticated molecular techniques were used and demonstrated that these strains were different. This finding is not unusual. Neonates are occasionally colonised with Gram negative bacteria but may not be infected, the organism may just be on the surface/in the bowel without causing any illness. The strains from the later babies were different, and unrelated to the outbreak strain.

23. Although other organisations/bodies had a role in assisting in the management of this outbreak, (e.g. Public Health Wales, the neonatal network) the role of these outside organisations are not considered as part of this review.

General Environment on the Neonatal Unit (NNU) at Singleton Hospital at the time of the outbreak

24. At the time of the outbreak, the NNU at Singleton Hospital was around 20 years old. The spacing of the cots and the general environment of the unit had been highlighted on the Women and Children's Directorate risk register[20] (although risk register did not include any detail as to how the

[20] ABMU Risk Register: Risk No 87. "**Risk posed by lack space in ITU/HDU on the neonatal unit to meet demand of the service.** Lack of adequate space around each cot space to meet infection control and BAPM environmental standards. Lack of WHBs. Current space per cot is 4m2; proposed improvement scheme would provide 8.4m2; recommended

risk was being managed at that point in time). The Health Board was planning to upgrade to new improved NNU area within Singleton Hospital as the NNU environment had already been recognised by the Health Board as being poor with dated facilities. Shortcomings in the environment included;

- an inadequate number of sinks within the area for the number of cots in use
- cracked and loose flooring and chipped surfaces to cupboards which had been identified by earlier infection control audits
- a central table within the NNU ITU area, where all staff would document in the baby notes; there was no co-location of notes near the individual cot spaces, increasing the risk of cross infection between staff members.

These concerns had been communicated to the Estates Department and a work plan was identified to prioritise areas of concern. The Health Board was unable to provide a precise date for when these concerns were communicated, but it is believed that they were present on the Women & Children's Directorate Risk Register from January 2010.

25. There were 6 cot spaces in each of the Intensive Care and High Dependency sections of the NNU. The layout of the Intensive Care and High Dependency sections made it a difficult environment when all 6 cots were in use (although they were only funded for 5 cots) as a significant amount of equipment was needed at each cot space.

26. The spacing between the cots on the Neonatal Intensive Care and High Dependency Unit within the NNU was less than 2 metres apart (centre of incubator to centre of incubator). This did not meet the standards set out in the '*British Association of Perinatal Medicine (2004)'.*

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area is 12m2 per cot. The risk is of HAIs, eg RSV"**.** Scored Consequence 5 x Likelihood 2 = 10. 'spaces will be achieved by the capital improvement scheme in 2011'..

Infection Control arrangements at the time of the outbreak

27. The Infection Control team at the Health Board consisted of 10.2 WTE Infection Prevention and Control Nurses, 2 WTE Infection Prevention and Control Nursing Assistants, 0.6 WTE Infection Prevention and Control Data Quality Co-ordinator, and 1 WTE Infection Prevention and Control Secretary and it did not have the provision for an identified Lead Infection Control Doctor. However the role was shared between the microbiologists, prior to and at the time of the outbreak. We understand that as of June 2012, an identified Lead Infection Control Doctor is in post.

28. ABMU HB organised mandatory training and skills study days for nursing staff, midwifery staff and support workers. They were all expected to attend on an annual basis. Infection control updates were included as part of these study days. The interviews with staff conducted after the incident indicated that the frequency of this training may not have been consistent. From the Root Cause Analysis and other reports we understand that staff received further training post the event. Medical staff however, only received hand washing training on their induction.

29. The NNU also had an Infection Control Link Nurse and dedicated 'Hand Wash Trainers'. They were responsible for carrying out regular environmental and hand washing audits. The Lewisham Hand Washing[21] audit tool was used on a monthly basis.

30. Infection Control was discussed at team meetings with staff receiving feedback following any audits carried out. Display boards were also in use around the NNU providing data from these audits.

[21] http://www.lewishamhealthcareipc.co.uk/microorganisms/washyourhands.php

Chapter 2: The Outbreak

Background to the incident

31. **Mother A** and **Mother B** were both transferred into ABMUHB from Prince Charles Hospital, Merthyr Tydfil (part of Cwm Taf Health Board) due to premature labour. Prince Charles Hospital is unable to accommodate premature babies of 27 weeks and below as it is not a level 3 NNU. Singleton's NNU can accommodate and care for premature babies of 27 weeks and below.

32. **Mother A** was admitted to Singleton Hospital on **29 October** at 26 weeks and 5 days gestation, and delivered **Baby A1** and **Baby A2** on 31 October 2011.

33. **Mother B** was admitted to Singleton on 26 October 2011 at 26 weeks gestation and delivered **Baby B1** on 31 October 2011.

34. Both **Mother A** and **B** delivered their babies via emergency caesarean section in Theatre 1 on the labour ward separated by twenty hours. There were 4 other deliveries in Theatre 1 that day.

35. Positive ESBL *E.coli* cultures were identified in **Baby A1**, **Baby A2** and **Baby B1**. **Mother A** also had a positive result of ESBL *E.coli* which had been confirmed by a vaginal swab taken on **29 October 2011** while at Prince Charles Hospital but not reported until **3 November 2011**.

36. Sadly **Baby B1** passed away on **4 November 2011** and **Baby A1** passed away on **8 November 2011**.

Chronology of key events

37. **Mother A** had received private In Vitro Fertilisation[22] (IVF) treatment (abroad) and conceived a twin pregnancy. At 14 weeks gestation a Shirodkar Suture[23] was inserted, however **Mother A** contracted ESBL *E.coli* (although it is unclear how this was contracted). This was reflected as a positive ESBL *E.coli* result and identified in **Mother A**'s medical notes from abroad which she had in her possession and declared them several days after the outbreak.

38. On **17 October 2011**, **Mother A** transferred her maternity care to Prince Charles Hospital in Merthyr Tydfil, part of Cwm Taf Health Board. **Mother A** was 25 weeks pregnant (gestation). On **28 October**, **Mother A** was admitted to Prince Charles Hospital in premature labour.

39. On **26 October 2011**, **Mother B** had spontaneous rupture of membranes and was experiencing cramp type pains. **Mother B** was 26 weeks gestation. **Mother B** was transferred to Singleton Hospital from Prince Charles Hospital. There was no evidence to suggest that the '*All Wales Intra Hospital Transfer Document'* had been completed on **Mother B's** admission to Singleton.

40. **Mother B** had previously had a cervical suture inserted while under the care of Prince Charles Hospital due to a high risk pregnancy and an incompetent cervix.

41. On **28 October**, at **09.20 hrs Mother B** was reviewed by a Consultant. It was agreed that the cervical suture should be removed and this was actioned at **17.15 hrs** that day. A High Vaginal Swab (HVS) was taken for culture and sensitivity. **Mother B** was transferred to the antenatal ward for observations.

[22] IVF is a process by which an egg is fertilised by sperm outside the body.

[23] Shirodkar Suture, also known as a cervical cerclage/ stitch is used for treatment of cervical incompetence (or insufficiency) to reduce the risk of miscarriage.

42. On **29 October** at **21.20 hrs**, **Mother A** was transferred to Singleton Hospital from Prince Charles Hospital where she had early premature labour and premature spontaneous rupture of membranes. Where there are transfers between hospitals, the '*All Wales Inter Hospital Transfer Documentation'* should be completed and sent with the woman's documentation to the receiving hospital. This documentation has the potential to alert staff to risk factors, although there is no specific question relating to women having treatment abroad or having contracted an alert organism. There is no evidence to suggest that this document was completed and sent to Singleton on this occasion nor was it requested by anyone at Singleton.

43. On **31 October**, the Shirodkar suture was removed from **Mother A** and later that afternoon premature labour progressed. This resulted in an emergency caesarean section and the delivery of **Baby A1** and **Baby A2** at 27 weeks gestation. **Mother A** delivered both **Baby A1** and **A2** in Theatre 1 on the labour ward. **Baby A1** was born at **00.40 hrs** and **Baby A2** was born at **00.41 hrs**. **Baby A1** was routinely resuscitated, incubated, given surfactant[24], ventilated and transferred in a transport incubator to the NNU. **Baby A2** did not require full ventilation at birth and was transferred separately to the NNU in a transport incubator on Continuous Positive Airway Pressure (CPAP). **Baby A1** was admitted into *cot space 3* of the ITU area within the NNU.

44. At **01.00 hrs**, **Baby A2** was admitted to the ITU in *cot space 2* of the NNU. **Baby A2** was in an incubator and was placed on advanced CPAP. As is normal **Baby A2** was commenced on IV Benzylpenicillin and Gentamicin.

45. At **02.40 hrs**, **Mother A** was transferred to the High Dependency area of the labour ward for routine postnatal care.

[24] Surfactants are compounds that lower the surface tension of a liquid, the interfacial tension between two liquids, or that between a liquid and a solid.

46. At **03.00 hrs** blood cultures were taken from **Baby A1** and as is normal IV Benzylpenicillin[25] and Gentamicin[26] was given. **Baby A1** had a raised CRP[27] (17) and suspected sepsis was noted by the medical team.

47. At **05.15 hrs**, the Consultant Neonatologist spoke to **Mother A** and her husband to discuss **Baby A1** and **A2's** condition. **Mother A's** husband visited both babies on NNU and both **Mother A** and her husband were aware that **Baby A1** was very unwell.

48. At **11.50 hrs Baby A2** was intubated and ventilated due to increased oxygen requirements but appeared in a satisfactory condition

49. **Mother A** visited the NNU at **13.30 hrs** to see **Baby A1** and **Baby A2**. Following this, Mother A was moved to the Low Dependency area.

50. However, at **20.05 hrs Mother A** showed signs of a fever with a rapid pulse rate. A management plan was drawn up which included investigations such as a chest and abdominal x-ray, blood cultures and blood gases. At **22.30 hrs**, there was communication between Singleton and Prince Charles Hospital regarding the results of **Mother A**'s previous vaginal swab which had been taken while **Mother A** was a patient there. Singleton were told the results would be available on **1 November**. **Mother A** was transferred back to the High Dependency area within the labour ward.

51. On **31 October**, at **19.55 hrs**, **Mother B** was urgently transferred back to the labour ward. The Paediatrician and Obstetrician examined **Mother B** and confirmed that she was 8cms dilated. However, a compound presentation was confirmed and a decision was made to transfer **Mother**

[25] Benzylpenicillin, commonly known as penicillin G, is the gold standard type of penicillin. 'G' in the name 'Penicillin G' refers to 'Gold Standard'. Penicillin G is typically given by a parenteral route of administration (not orally) because it is unstable in the hydrochloric acid of the stomach.

[26] GentamIcin is an antibiotic, used to treat many types of bacterial infections, particularly those caused by Gram- negative organisms

[27] CRP: C-reactive protein is a protein found in the blood, levels of this protein may rise if there is infection or inflammation.

B to theatre for an emergency Caesarean Section. At **20.43 hrs Mother B** delivered **Baby B1** in Theatre 1.

52. **Baby B1** was intubated and transferred to the NNU via a transport incubator. **Baby B1** was accommodated in *cot space 4* in the ITU. As is normal **Baby B1** was commenced on IV[28] Benzylpenicillin and Gentamicin.

53. At **21.30 hrs Mother B** was transferred to the low dependency area of the labour ward

54. Between **1** and **2 November**, **Mother A** continued to manifest signs of infection and screening for Malaria[29] was undertaken. The results however, were negative.

55. On **1 November** at **10.39 hrs**, **Baby B1** appeared well and was intubated and ventilated and given surfactant. Later, at **16.00 hrs Baby B1** was extubated and placed on CPAP[30].

56. On **1 November Mother B** was transferred to the post natal ward for routine postnatal care. Results from the HVS identified a heavy growth of beta-haemolytic streptococcus group B[31] and *E.coli* which was fully sensitive[32]. It was recorded in the notes that **Mother B** visited **Baby B1** on the NNU frequently.

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[28] IV

[29] Malaria is a mosquito- borne infectious disease caused by a bite from an infected female mosquito.

[30] Continuous positive airway pressure (CPAP) is the use of continuous positive pressure to maintain a continuous level of positive airway pressure.

[31] A normal bacterium found in around 30% of the population, without symptoms or side effects. It is believed that around 25% of women carry it in the vaginal tract which causes them no problems whatsoever.

[32] This was a completely unrelated strain to the ESBL *E.coli* that Mother A, and Babies A1, A2 and B1 had. Most *E.coli* strains cause no problems at all and are normal residents in the gastrointestinal tract. Fully sensitive: the growth of the organism is inhibited by the action of the drug/antibiotic.

57. On **1 November** at **04.45 hrs Baby A1**'s CRP[33] was recorded as 48 and blood cultures were taken again. **Baby A1** continued to show signs of infection and a lumbar puncture was performed at **20.10 hrs**. The CSF[34] result was recorded as normal and no organism was found. **Baby A1**'s medication was changed to Vancomycin[35] and Cefotaxime[36] in an attempt to counter the signs of infection.

58. On **1 November**, **Baby A2** still appeared well and was extubated and placed back on CPAP.

59. On **2 November** at **03.23 hrs**, **Baby B1** required increased oxygen. The Consultant Neonatologist was informed and a plan was made to x-ray **Baby B1** to rule out pneumothorax[37] and to consider re-intubation. The x-ray showed right upper lobe collapse and at **09.00 hrs Baby B1** was re-intubated without any problems. Throughout the day **Baby B1** remained well, although the baby had developed high blood glucose levels which required an insulin infusion.

60. At **10.00 hrs** on **3 November** the Microbiologist (from ABMUHB) advised staff at the NNU that the High Vaginal Swab (HVS) (taken on **29 October** while **Mother A** was at Prince Charles Hospital) had grown ESBL *E.coli*. **Mother A** was prescribed Meropenem[38] antibiotics for 5 to 7 days. The Microbiologist advised that further cultures should be taken before changing antibiotics and to review with the Microbiologist after 5 days for an update. At **12.00 hrs** a telephone call from the infection

[33] C-reactive protein (CRP) is a protein found in the blood, the levels of which rise in response to inflammation (i.e. C-reactive protein is an acute-phase protein).

[34] CSF: Cerebrospinal fluid is a clear colourless body fluid around the brain and spinal cord, if clinicians suspect meningitis they may sample this fluid.

[35] Vancomycin is an antibiotic used in the prophylaxis and treatment of infections caused by Gram- positive bacteria.

[36] Cefotaxime is a third-generation antibiotic. Like other third-generation cephalosporins, it has broad spectrum activity against Gram positive and Gram negative bacteria.

[37] A pneumothorax is an abnormal collection of air or gas in the pleural space that separates the lung from the chest wall and which may interfere with normal breathing

[38] Meropenem is an ultra-broad spectrum injectable antibiotic used to treat a variety of infections.

control team advised the NNU that resistant[39] *E.coli* was reported on **Mother A**'s HVS report and that barrier nursing[40] procedures should be put in place. The registrar discussed the HVS report with **Mother A** and she was transferred from the high dependency area into a cubicle on the labour ward where Barrier Nursing procedures were implemented.

61. On **3 November** at 13:30 hrs the Microbiologist contacted the NNU to advise that a microbiological specimen taken from **Baby A2** had grown ESBL *E.coli*. Since **Baby A2** was well, this indicated colonisation. The decision to barrier nurse both **Baby A1** and **Baby A2** was taken, although no confirmed result had been received for **Baby A1**. **Baby A1** was too unwell to move into a cubicle so barrier nursing procedures were implemented in the incubator whilst **Baby A1** remained in cot space 3 of ITU.

62. The microbiologist reassured the NNU staff that the infection could be controlled in the incubator providing that universal barrier nursing procedures/ precautions were in place. **Baby A1** received 1:1 nursing care and following advice from microbiology, **Baby A1** was commenced on Meropenem antibiotics.

63. On **3 November Baby B1** was reviewed regularly throughout the day. However, at **16.30 hrs**, **Baby B1** looked pale and showed a mild metabolic acidosis. Later that evening, at 22:00 hrs, **Baby B1** was prescribed Meropenem antibiotics and blood cultures were taken.

64. On **4 November** at **00.20 hrs**, **Baby B1**'s heart rate fell to 50-60 beats per minute. Despite good ventilation and resuscitation **Baby B1**'s condition continued to deteriorate and sadly **Baby B1** died at **01.00 hrs**. Later on **4 November** at **07.00 hrs Mother B** was discharged home.

65. On **4 November**, at **04.50 hrs** the Consultant Neonatologist visited **Mother A** and her husband to discuss the condition of **Baby A1**. **Mother**

[39] Resistant: not susceptible to the antibiotic.

[40] Barrier nursing is a term given to a method of nursing care when caring for a patient known or thought to be suffering from a contagious disease.

A's husband visited NNU to see **Baby A1**. At **09.15 hrs**, maternal observations were recorded as normal. A request for a scan, repeat bloods and a physiotherapy review were made. However, the Diagnostic Imaging Department would not undertake **Mother A**'s scan due to her having an *E.coli* infection. The Consultant was informed of this decision and as **Mother A** was improving, he decided that the abdominal scan was not required providing her C-reactive Protein[41] (CRP) was decreasing.

66. On **5 November** blood cultures confirmed that **Baby B1** had contracted ESBL *E.coli*.

67. Between **4** and **6 November Baby A1** continued to be very unwell and showed signs of deterioration. **Baby A1** was confirmed to have contracted ESBL *E.coli* on **6 November** and continued to be treated with Meropenem.

68. On **6 November**, **Mother A** was concerned about both **Baby A1** and **A2** as she was unable to visit. **Mother A** was later reviewed by the Registrar. It was noted that **Mother A** was clinically well but continued to spike temperatures. At **12.00 hrs** (midday) **Baby A1** remained poorly, but **Baby A2** was noted to be improving.

69. On **7 November**, **Baby A1** became critical with severe sepsis identified and was commenced on high ventilation.

70. At **12.30 hrs** on **8 November**, the Consultant spoke with **Baby A1**'s mother on the labour ward and advised of **Baby A1**'s deterioration. **Baby A1** had developed a very large intracranial haemorrhage[42]. On **8 November** at **14.00 hrs**, the Consultant Neonatologist visited **Mother A** and her husband to discuss withdrawing treatment from **Baby A1**. This was agreed and at **15.15 hrs** intensive care was withdrawn.

[41] C- reactive protein is a protein found in the blood, the levels of which rise in response to inflammation
[42] An intracranial haemorrhage (ICH) is a haemorrhage, or bleeding, within the skull.

71. Sadly, at **17.10 hrs Baby A1** stopped breathing. At **17.30 hrs Mother A** was informed by the Consultant Neonatologist that **Baby A1** had passed away.

72. On **9 November**, **Mother A** advised the Medical Team that she had notes of the treatment that she had previously received whilst abroad. These notes were requested and reviewed by the medical team and it was noted that multi-resistant ESBL *E.coli* had been identified in urine samples taken abroad. These notes had not been requested by staff previously.

73. From **9 November Mother A** continued to improve and was discharged home on **12 November**. Between **4** and **17 November Baby A2** remained well and continued to be barrier nursed in a cubicle on NNU.

74. On **17 November**, **Baby A2** was transferred to Prince Charles Hospital, Merthyr Tydfil for ongoing care. **Baby A2** was eventually discharged home on **29 December**.

Chapter 3: Our findings

75. In this chapter we will set out the key findings identified by our review.

Health Board outbreak management policy: Hospital arrangements for Incident/Outbreak Control

76. It is important that all organisations providing healthcare have an outbreak management policy. The ABMU Health Board's policy entitled *"Infection Outbreak/Incident Management on Hospital Premises"* produced by the Department of Infection Prevention & Control was issued in January 2011 and was applicable at the time of the ESBL *E.coli* outbreak in the Singleton NNU.

77. Section 4, of the policy sets out the general responsibilities of the Health Board and managers/Clinical Directors/Locality Directors. Other sections cover:

- Recognition of a Hospital Outbreak (Section 5)
- Verification and assessment of reported hospital outbreaks (Section 6)
- Investigation of the hospital outbreak (Section7)
- Management of an infection incident in hospitals (Section 8)
- Management of a hospital outbreak of limited extent (Section 9)
- - Members of the Hospital Outbreak Control Team (Section 9.4)
- - Functions of the Hospital Control team (Section 9.5)
- Management of a major outbreak (Section 10)
- Audit (Section 11)

- Other arrangements are outlined in the appendices of “Infection Outbreak/Incident Management on Hospital Premises”.

Recognition of a Hospital Outbreak: General principles

78. Early identification and control of an outbreak requires implementation of the Health Board’s existing procedure and guidelines. Clarity regarding roles and responsibilities of individuals is important.

79. Detection of an outbreak relies on the recognition of a cluster of cases during a short period or longitudinally over a period of months. Cases may have infections or just colonisation (generally this means the organisms is on the skin or mucous membranes but not causing an infection, in some instances the word “carrier” is used to describe colonisation).

80. Sometimes, if cases are spread over a period of time (weeks or months), unless a proper surveillance system is in place, detection might take longer or missed altogether. Detection does require an active conscious action, this could be at the laboratory level by the biomedical scientists on the bench noticing a series of cases in a unit or wards or across a number of wards or an unusual pattern, or at an infection control team level observing alert organisms, or at a ward level by healthcare staff (nurses and doctors) monitoring results.

81. Detection outlined above can only occur if clinical or screening specimens are submitted to the microbiology laboratory for examination. Generally, identification of a colonising or infecting pathogen may take between 24-72 hours from the receipt of the specimens. Screening for Gram negative pathogens is not routinely performed and at present there is no guidance on when this should be done but generally once there is suspicion of an incident, screening of all neonates on the unit should be initiated to determine the extent of the problem/colonisation.

82. As mentioned previously, there is not one particular moment when an outbreak may have been deemed to have occurred, unless it is a point source outbreak. Information becomes available over a course of days. At a particular moment in time, when healthcare workers or members of the infection prevention and control team are concerned about a few colonised or infected cases and the possibility of an outbreak, does a formal process of investigation start. Once these deliberations are made a decision would be made to declare an outbreak.

83. The declaration of an outbreak is an enabling action and facilitates things to happen. Amongst other things it formalises the processes and procedures by holding regular outbreak management meetings involving a multidisciplinary group, working to an action plan and action list with updates on the situation and progress on the implementation and completion of infection prevention and control measures, such as closure of a ward. In addition, the presence of executives enables additional resources to be made available easily and a more formal method of communication to external statutory bodies and partners opened. For the ABMU Health Board these are detailed in the document: “Infection Outbreak/Incident Management on Hospital Premises”.

84. There are epidemiological and microbiological definitions of an outbreak but the above describes the normally pragmatic approaches used by acute care providers.

Recognition of a Hospital Outbreak – ABMUHB

85. A brief outline of some key events leading up to and during the outbreak is provided below:

Patients

86. On the 31 October 2011 at 00.40hrs, Mother A delivered twins by caesarean section. The twins (Baby A1 and Baby A2) were admitted to

the NNU at 01.02hrs and 00.57hrs in Incubator Cot 3 and Incubator Cot 2 respectively.

87. On the same day (31 October 2011) at 20.43hrs Mother B delivered a 26 week gestation baby by caesarean section. Baby B1 was admitted to the NNU at 21.00hrs in Incubator Cot 4.

88. Routine and clinical maternal and neonatal specimens were sent to the microbiology laboratory between admission/ birth and post-delivery clinical assessment.

The Neonatal Unit (NNU)

89. At the time of the outbreak there was evidence to suggest that there was a peak in the service, with a greater number of babies on the NNU which required high levels of care. This increased acuity and demand on the service, required increased nursing levels.

90. We were told by staff that during the period prior to the recognition of the outbreak the NNU was particularly busy. On 3 November 2011 at 08:00 hrs the unit was caring for 7 intensive care babies, 1 high dependency baby and 5 special care babies – a total of 13 babies. The babies required 8.75 nurses according to BAPM recommendations. There were 9 staff on clinical care in the morning, 8 nurses on clinical care in the afternoon and 9 nurses on clinical care on the evening. In the preceding 48 hours the acuity was similar.

Outbreak recognition

91. The first microbiology results confirming ESBL *E.coli* seem to have been available on Thursday 3 November 2011 at 10.00hrs when a microbiologist contacted the maternity unit clinicians and reported that an ESBL *E.coli* had been isolated from Mother A's high vaginal swab taken on the 30 October 2011. This was a clinical consultation and there is no mention of any infection control advice having been given.

92. At 12:00 hrs on 3 November 2011 infection control phoned the post natal ward to report a resistant *E.coli* and express the need for Mother A to be barrier nursed. At 12.20 hrs the Obstetric Registrar informed Mother A of the result and the need for barrier nursing.

93. At 13.30 hrs 3 November 2011, the microbiologist left a telephone message on the NNU that ESBL *E.coli* had been isolated from an endotrachael aspirate (ET) taken from Baby A2, sensitivities were provided. The neonatologist spoke to a consultant microbiologist at 13.30hrs and confirmed that the mother was being treated.

94. Transmission of ESBL *E.coli* to Baby B1 probably occurred between 9pm Monday 31 October 2011 and Thursday 3 November 2011 on the NNU. Baby B1 seemed to deteriorate late afternoon on the 3 November. At 4:30pm the baby was reported to have had a poor blood gasses with metabolic acidosis (pH of 7.16), lactate 1.9 mmol/L, the baby looked pale. At 5:00pm a slight improvement was noted, pH 7.21, however the lactate had risen to 3.9 mmol/L. A blood transfusion was commenced at 7:25pm. At 10:00pm the baby looked very pale, the blood gas was much worse and had developed a severe metabolic acidosis pH 7.04, and lactate was 7.0 mmol/L. There was a strong suspicion of sepsis. The baby was given a dose of Meropenem and Gentamicin was continued and benzyl penicillin was discontinued.

Immediate Steps/Actions

95. During the conversation between the neonatologist and the microbiologist at 13:30 hrs 3 November 2011 infection control issues were discussed. Barrier nursing was commenced on both twins, Baby A1 and Baby A2. Baby A1 remained in NNU cot space 3 as the baby was too ill to move. Baby A2 was moved to the cubicle adjacent to the main unit. At this point 1:1 nursing was in place for Baby A1. All staff were updated on the need for strict aseptic precautions.

96. Later that evening (3 November 2011) at 21.30 hrs, a microbiologist phoned the NNU. No growth was reported on blood cultures taken on 31 October 2011 and 1 November 2011 and the cerebrospinal fluid (CSF) taken on 1 November 2011 from Baby A1. However, Gram negative bacilli had been detected from the blood cultures taken from Baby A1 earlier on the 3 November 2011.

97. The microbiologist advised the continuation of antibiotics and infection control advice was reinforced

98. At this time there was only one proven case of a baby being colonised with ESBL *E.coli*, Baby A2 who was nursed in a cubicle. At 21:30 hrs on 3 November 2011 Gram-negative organisms in the blood of Baby A1 were reported to the unit but this was not yet confirmed as *E.*coli nor ESBL *E.coli.* At this stage Baby B1, in the neighbouring cot, incubator Cot space 4 on the unit was suspected to have sepsis.

99. At 22.00hrs on 3 November 2011 Baby B1's antibiotics were changed to meropenem, an antibiotic that is active against ESBL producing organisms.

100. As a precautionary measure the consultant neonatologist closed the NNU to new admissions at around 22:00hrs.

101. Unfortunately, during the early hours of Friday 4 November 2011 (01.00hrs) Baby B1 tragically succumbed to the infection. Intracardiac aspiration blood cultures were taken from Baby B1 later on 4 November following death.

102. As a precaution Meropenem was commenced on Baby A2 on 4 November 2011, the neonate continued to be barrier nursed and remained well.

103. The next morning, Saturday 5 November 2011, ESBL *E.coli* was confirmed from the intracardiac aspiration blood cultures taken at

01.00hrs on 4 November from Baby B1. The records note that the isolate was sensitive to Meropenem but resistant to Gentamicin.

104. During the period from the 3 November to 8 November Baby A1 remained unwell and a large grade IV and grade I intraventicular haemorrhage was detected in the right and left brain respectively. Unfortunately, Baby A1 died at 17.10 on Tuesday 8 November 2011.

105. Although, the rectal swabs continued to grow ESBL *E.coli*, Baby A2 remained well and was discharged back to Prince Charles Hospital on 17 November 2011.

Summary of the microbiology

106. It is not clear from the documentation made available to HIW whether the organism was sensitive or resistant to gentamicin. It is also not clear why the original microbiology samples from Mother A took so long to confirm the presence of ESBL *E.coli*.

Opportunities prior to the Outbreak

107. It is difficult to assess whether the availability of Mother A's medical records/microbiology results or the mention of ESBL *E.coli* on the "*All Wales Transfer form*" would have made a significant impact on the subsequent management of the patients in terms of isolation. This is dependent on what actions healthcare workers might have taken and any comment would have been pure speculation at this stage.

108. The factors that are important are whether a baby born to a ESBL *E.coli* colonised or infected mother would have been isolated or have had strict 1 to 1 nursing. A great deal of reliance is placed on the individual healthcare worker's responsibility to maintain rigorous infection prevention and control practice and on the need for best practice in terms of a clean environment (patient areas) and use of adequately decontaminated or sterile equipment.

109. In particular, the NNU was a cluttered area with very little space between cots. Equipment, such as the Ultrasound and X-Ray machines, was being shared between cots. Importantly, there were only two sinks for hand washing in the 6-bedded NNU although there was hand washing facilities in other parts of the unit. This was clearly insufficient and significantly raised the risks of cross infection in terms of potential hand hygiene infection control issues. Opportunities for hand hygiene would have been available at the alcohol gel stations.

110. The NNU environment was not an optimal area to deliver the safe intensive care required to the babies on the unit at the time of the incident. This had been previously recognised by the Health Board and plans were in fact in place at the time of the incident to upgrade the unit in January 2012.

Detection of the Outbreak

111. The key events and activities of 3rd November 2011 indicate that there was a suspicion that something was evolving on the unit. This began at the relaying of Mother A's microbiology results to the post natal ward in the morning. The conversations between the microbiologist and neonatologist about the babies' microbiology results at 1.30pm, the decision to isolate where possible and provide 1 to 1 nursing and heightening infection control awareness were considered, and demonstrated the need for further action.

112. The subsequent, out of hours, discussions between the microbiologist and neonatologist at 9pm seem to reinforce these concerns and the acuteness of the situation. At some point that evening the connection between the ESBL *E.coli* colonised/infected babies (Babies A1 and A2) and the sick Baby B1 was made and this led to the decision to close the unit to new admissions and to change the antimicrobial therapy for Baby B1. Sadly, this came too late for Baby B1 who died within a few hours of those decisions having been made.

113. On 5 November, the intracardiac blood culture results on Baby B1 reported an ESBL *E.coli* bacteraemia confirming the previous suspicions.

Outbreak Control Team and Management of the Outbreak

114. One of the essential components of outbreak management is the need for an outbreak management team with the appropriate membership. The incident and outbreak control meetings held by the Health Board at the later stages were appropriately attended by multidisciplinary group members and executive representatives.

115. Two initial meetings were held on the 7 and 8 November chaired by the Head of Nursing. These were not formal Outbreak meetings. Attendees included a mixture of key clinicians and midwives, in addition to infection control staff and microbiology consultants. However, we question why the first meeting did not take place until 7 November, when an outbreak was feared on 3 November (with the NNU being closed to new admissions) and definitively on 5 November.

116. At these meetings, all the facts surrounding the incident were gathered and immediate actions were identified. These included:

- Immediate cleaning
- Greater spaces between cots on the NNU (reduction from 6 cots to 3)
- All babies to be screened for ESBL *E.coli*
- NNU to be on Red Alert
- Swabs to be taken from all babies on the NNU
- Informing the Neonatal Network
- Public Health Wales to be contacted
- Director of Nursing to be informed

117. We were told that the Chief Executive was informed of the outbreak verbally on Tuesday 8 November 2011. An outbreak management team initially met on 9 November 2011 to discuss the events on the NNU and was chaired by the Director of Nursing, and was appropriately attended by multidiscipline professionals. The formal declaration of an outbreak was therefore made on Wednesday 9 November 2011 at the Outbreak Control Group Meeting. However, it is unclear precisely when the outbreak was communicated to the executive team from the documents provided. Most of the *outbreak* meetings were chaired by an Executive Director; the Director of Nursing and the Medical Director chaired at least one meeting each. The notes indicated that the Chief Executive visited the NNU and chaired a meeting.

118. Points discussed at the initial formal Outbreak meeting included:

- The initial screening results of all babies had come back as negative
- Increased cleaning to be implemented
- Tight infection control procedures to be adhered to
- Continue with increased spacing between cots on the NNU
- The Merthyr area Microbiologist to be contacted
- Root Cause Analysis/Timeline to be completed within 2weeks
- Welsh Government to be informed

119. Several further Outbreak Control Group Meetings were then held. These convened on:

- Monday 14 November 2011

- Thursday 17 November 2011
- Monday 21 November 2011
- Friday 25 November 2011
- Monday 28 November 2011
- Monday 5 December 2011
- Friday 9 December 2011
- Monday 12 December 2011
- Tuesday 17 January 2012
- Thursday 22 March 2012

120. These subsequent meetings were used to manage the Outbreak and various action plans were developed. Further investigations were also carried out and reported at the respective Outbreak Meetings.

Communications

121. At the Outbreak Meeting held on 14 November 2011, discussion was held regarding a Communications Plan. It was agreed that the communication plan needed to include communication with all families/patients involved, Welsh Government, other stakeholders and staff.

Parents

122. During this outbreak period consultant neonatologists appropriately kept the parents of Babies A1, A2 and B1 informed of their clinical condition and also informed the respective parents of the tragic news when their babies succumbed to their illnesses.

123. The Health Board had to determine the best time to inform the parents of the possibility of the death of their babies being linked to the outbreak. The minutes from the Outbreak Meeting held on 14 November reflect that this was considered in some detail, given the sensitivities of the situation. A written statement was given to the parents along with an information sheet on ESBL *E.*coli on 19 November 2011.

Media

124. In the third week of November, after further colonised neonates were discovered the Health Board made a statement[43]. This story was widely covered by the local and national press and media.

Formal declaration of the outbreak

125. The Outbreak was not formally declared until 9 November 2011 during the first Outbreak Control Group Meeting. The Health Board has recognised that the reporting of this outbreak could have been done in a more timely fashion. It is important that stakeholders and partners are informed of such events swiftly so that any help/support or rearrangement of service delivery is required from these organisations when a wider view is taken these can be mobilised earlier.

126. Whilst in this instance it would have made little or no difference to the outcome for Babies A1 and B1, however the importance of this can not be underestimated.

Formal closure of the outbreak

127. The minutes from the Outbreak Control Group Meeting held on 17 January 2012 confirmed that the outbreak had been formally concluded. While a further Outbreak Control Group Meeting was held on 22 March

[43] http://www.wales.nhs.uk/sitesplus/863/news/21082

2012, it was decided at that meeting that there was no requirement for any further Outbreak Control Group Meetings.

In summary: The Hospital outbreak response

128. On occasions it is immediately apparent that an outbreak has occurred, at other times it is generally difficult unless the same organism has been identified in two individuals within a short period of time.

129. There was a situation developing on the 3 November. Mother A1's results were available at 10:00 hrs. The conversation about ESBL *E.*coli did occur at 13:30 hrs. A decision was made to move Baby A2 to a side room. We understand that Baby A1 could not be moved because of its clinical condition. However at this stage there was no connection made with Baby B1. Baby B1 was noticed to be deteriorating at 16:30 hrs and the lactate was rising over the course of the next few hours. The microbiologist phoned at 21:00 hrs and reported the blood cultures positive on Baby B1. Meropenem was commenced at 22:00 hrs for Baby B1. It is difficult to determine if these associations could have been made earlier and what difference it would have made to the clinical outcome for Baby B1.

130. We also believe that the screening of all the babies in the NNU should have commenced on 5 November. We question why there was a delay in screening.

131. The general response once the outbreak was formally recognised was reasonable. The unit was closed to admissions, hand hygiene was reinforced, the unit was deep cleaned and the number of cots in the unit was reduced. In addition, the Outbreak Meetings were held at regular intervals including key representation from across the Health Board, and it is clear that this outbreak was dealt with as a very serious incident with efforts being made to ascertain the cause of the outbreak.

132. We also query the speed of the communication made with the other families and patients who had been or were currently on the NNU. Whilst we appreciate the sensitivity of the situation, in particular in regards to Mother A and Mother B, it took until at least 14 November for the Health Board to directly communicate with families of babies currently on the NNU.

Chapter 4: Summary and Conclusion

133. It is hugely regrettable that during the period 3 November 2011 and 9 November 2011, two babies tragically lost their lives on the Singleton NNU.

134. While both babies were premature and already in need of intensive care a failure of infection prevention and control between 31 October and 2 November 2011 resulted in the transmission of an Extended Spectrum Beta Lactamase producing *Escherichia coli* from one baby to another baby on the Singleton Hospital NNU. The infections contributed to the deaths of the two premature babies. Vertical transmission contributed to the death of one premature baby (A1) and horizontal transmission contributed to the death of another baby (B1). However, the spread was limited. No other babies on the unit were affected by this unique outbreak strain of ESBL *E.coli*.

135. An infection transmission event occurred which led to the adverse outcome in Baby B1. It is extremely difficult to determine exactly when this transmission event occurred or whether it was due to a failure in hand hygiene or a failure in infection prevention and control. Nevertheless, the fact that the transmission event occurred is *strongly suggestive of a failure in hand hygiene or in infection prevention and control* and probably occurred during the period 31 October and 2 November, as by the evening of 3 November Baby B1 was showing signs of infection.

136. The immediate actions taken by the staff on the NNU, infection control team and the outbreak management team on behalf of the ABMU HB contained the incident and prevented further spread and limited harm to other neonates.

137. Reinforcing infection prevention and control, raising awareness of the potential problem and the neonatologist's decision to close the NNU to

admission probably averted further tragedies in this busy unit. These actions will have highlighted to staff and others the need to reinforce infection prevention and control practice. Without these actions the situation may, or could have been much worse.

138. The incident and outbreak management teams initially met daily and then weekly. In general, the meetings were attended by a multidisciplinary group and led by an executive. This was in accordance with the ABMU Health Board's policy entitled "Infection Outbreak/Incident Management on Hospital Premises" produced by the Department of Infection Prevention & Control was issued in January 2011

139. During the period 7 – 9 November a number of relevant actions were taken including specific screening for ESBL *E.coli.* This screening did reveal other babies who were colonised with ESBL *E.coli* but these were subsequently found to be a different strain from the outbreak strain.

140. At the time of the outbreak the conditions were cramped, activity was high and hand washing stations were limited. The Health Board had already identified the care accommodation as one of its priorities areas and plans were already being compiled for improvements in this area. The NNU visit by the Chief Executive Officer, the completion of the of root cause analysis process and report and staff interview exercise provided ABMU HB with valuable insight into the areas where improvements were required.

141. The NNU moved temporarily to another area of the hospital on 19 June 2012 to mitigate against the poor environment of the original unit. This temporary relocation to an area where the spacing of cots and hand hygiene station facilities was a positive action going some way towards minimising some risks of infection. As of July 2013 the NNU relocated back to the newly modernised original unit.

142. This temporary relocation allowed ABMU HB an opportunity to modernise the NNU facilities. However, this alone will not wholly minimise future cross infection risk and is only the physical aspect of

minimising cross infection risk; improvements in individual and organisational behaviour and culture will allow a more sustained and long term improvement in minimising cross infection and improved care. It is encouraging that the CEO showed leadership by visiting the unit and was supported by the executive in managing this outbreak and the decisions to relocate and modernise the unit taken swiftly.

143. Individual and organisational practices need to be improved and these can only be assessed after a period of time has lapsed and the need for improvements in training highlighted in the staff interview exercise has been implemented.

144. The Health Board has now appointed an identified Lead Infection Control Doctor (as of June 2012) who will strengthen the infection control team and provide more focused support. Given that weaknesses in hand hygiene practices amongst medics is an issue that was apparent within the NNU we hope that this appointment will assist in strengthening focus in relation to this area. The Health Board needs to continue investment in a regular infection control training programme. We cannot emphasise enough the requirement for the Health Board to strengthen infection control and hand hygiene practice amongst all staff.

145. We also believe that a risk assessed admission policy supported by adequate isolation facilities where intensive care can be provided and adequately resourced and staffed is required. The review of neonatal services within the Wales reorganisation programme should provide further flexibility and support to the overall NNU service in Wales.

146. Early closure prevented other babies from being exposed. Screening, although delayed, identified the spread of the infection. The subsequent infection, prevention and control measures stemmed the outbreak and protected other babies from being infected. Whilst we feel that the outbreak meetings could have been held earlier, this would not have affected the outcome in this case.

Chapter 5: Recommendations

In relation to the Health Board:

Recommendation 1

The NNU with the help of the Infection Control Team and the medical microbiologists should devise an early warning system to alert the neonatologists and Neonatal Unit staff of alert organisms likely to lead to a transmission incident/outbreak.

Recommendation 2

Data monitoring unit activity and staffing is collected on an on going basis. During sickness and shortage of staffing, agency staff are not allowed to be employed. This does lead to difficult situations.

The Health Board should develop an appropriate system to monitor unit activity and staffing and provide an early provision of adequate resources when activity is not matched with safe levels of staffing resources to maintain patient safety[44].

Recommendation 3

Clinical staff reported receiving infection control training after the outbreak. It is important that infection control becomes a natural extension of clinical good practice in the NNU and not something that has to be enhanced in the event of an incident/outbreak. A proactive approach rather than a reactive approach would be preferable.

The Health Board should reinforce its continuing infection prevention and control training programme for all staff. This should be mandatory and monitored – non compliance should lead to a failure

[44] In line with 'Chief Nursing Officer Guiding Principles for Nurse Staffing Levels Wales April 2012'

in appraisal. Visual monitoring and challenge should become the norm in regards to infection prevention and control[45].

Recommendation 4

It is recognised that staff will be reluctant to transfer sick neonates to other institutions during an incident/outbreak however; the Health Board and the local Neonatal Network should devise an action plan, similar to a major incident plan, for the safe transfer or local management of neonates and develop the criteria for this to occur should the situation require.

Recommendation 5

The Health Board should ensure that there is provision for easily accessible hand washing stations in compliance with national standards[46].

Recommendation 6

The Health Board should review its visitor policy. This should take into account children, visitors, requirements for parents and rules around NNU etiquette. Similar guidance for NNU staff working on the unit and visiting should be developed.

Recommendation 7

As part of the strategy to prevent future outbreaks and although this was not a water system related incident, the Health Board should

[45] The principles outlined in the NICE/HPA Quality Statements (Nov 2011) should be adopted by the Health Board and relevant sections should be adopted. See: http://www.nice.org.uk/guidance/PH36

[46] See: http://www.bapm.org/publications/documents/guidelines/DesigningNNU_May2004b.pdf

comply with the Welsh Government statements on Water Supply and management[47].

In relation to the Neonatal Network:

Recommendation 8

The Neonatal Network should look at this incident, extract the lessons learnt and disseminate this learning to all NNU's in Wales to ensure that the risk of such a future event is minimized – staff at all levels and grades should be involved.

Recommendation 9

The Neonatal Network should look at other units within its geographical area and ensure that units have adequate space and staffing levels. Concerns in regards to this should be communicated to the relevant Health Boards highlighting the risks and request they urgently correct any deficiencies in these areas.

Recommendation 10

The Neonatal Network should review its arrangements to ensure that when outbreaks of this nature occur, the Network is able to absorb the closure of a NNU, taking into consideration that this will increase pressure on the Network itself.

Recommendation 11

As part of the strategy to prevent future outbreaks and although this was not a water system related incident , the NNUs within the

[47] See: http://wales.gov.uk/topics/health/ocmo/publications/cmo/item/water/?lang=en

See: http://wales.gov.uk/topics/health/ocmo/publications/cmo/item/contamination/?lang=en

Neonatal Network should comply with the Welsh Government statements on Water Supply and management[48].

In relation to Welsh Government and Public Health Wales:

Recommendation 12

Public Health Wales and Welsh Government should consider undertaking a review of the common causes of NNU outbreaks. The outcome of this review and the learning points for best practice should be disseminated to all Health Boards. The Health Boards should adopt the learning. After a suitable period, an audit should be completed to provide assurance of best practice/compliance.

Recommendation 13

Welsh Government should review the '*All Wales Inter Hospital Transfer Documentation*' to ensure that this documentation sufficiently captures any information that may refer to treatment received abroad.

[48] See: http://wales.gov.uk/topics/health/ocmo/publications/cmo/item/water/?lang=en

See: http://wales.gov.uk/topics/health/ocmo/publications/cmo/item/contamination/?lang=en

Annex A

Terms of Reference

HEALTHCARE INSPECTORATE WALES
INDEPENDENT REVIEW OF THE MANAGEMENT OF ABERTAWE BRO MORGANNWG UNIVERSITY HEALTH BOARD'S (ABMU) RESPONSE TO THE ESBL *E.COLI* CROSS INFECTION IN THE MATERNITY/NEONATAL UNIT AT SINGLETON HOSPITAL

Healthcare Inspectorate Wales (HIW) is to undertake an independent review of Abertawe Bro Morgannwg University Health Board's response to the outbreak and cross infection of ESBL *E.coli* that occurred at the maternity/neonatal unit at Singleton Hospital, Swansea i**n November** 2011. This outbreak resulted in the death of one premature baby at the maternity unit in Singleton. The subsequent death of a second baby was found to be due to an infection that was contracted outside the hospital.

This review will commence after the Health Board has concluded its own internal investigation.

Terms of Reference

HIW will undertake a focused review to ensure that the Health Board:

- took all reasonable steps to identify and address the cause(s) of the cross infection.
- managed the matter in an effective and timely manner that avoided further incidents of cross-infection.
- has learnt from the incidents and put in place arrangements that will minimise future cross infection.

HIW will report upon its findings and make any recommendations it sees fit to ensure any necessary improvement to the safety of services and the safeguarding of service users.

Annex B

The Organism - Escherichia coli

Most strains of *Escherichia coli* form part of the normal intestinal microflora in humans and warm-blooded animals. These are described as commensals, they exist in that environment and do not cause any harm.

Some strains have the ability to cause disease in humans through the presence of specific virulence factors.

In humans, most infections of this pathogen are related to urinary tract infections. In complicated urinary tract infections, bacteraemia (infection in the blood) occurs in some patients. This may lead to septicaemia causing the heart rate to increase and the blood pressure to drop, leading to multi-organ failure and subsequently to death.

Treatment for sepsis may require intensive care and a twofold approach is taken:

(i) supportive to maintain the blood pressure and alleviate organ failure (respiratory failure and renal failure) by assisted ventilation and renal dialysis;

(ii) specific antimicrobial treatment directed against the infective organism. Simple infections can be treated with oral antibiotics and more complicated infections require intravenous therapy.

When these infections occur within a hospital setting they are mostly called healthcare associated infections. Occasionally, these infections occur because the devises used to monitor and support patients become colonised with pathogens which then may lead to infection. Devices for vascular access (peripheral, central, arterial and umbilical lines) and urinary catheters are known to be prone to such colonisation leading to infection. Endotracheal

tubes required for mechanical ventilation may become colonised, this may lead to pneumonia. Occasionally, these infections can be serious as described above and may in some instances lead to death. Sometimes, an invasive infection may occur after surgery and bowel surgery may be more prone to an infection of this type than other types of surgery.

When these organisms are derived from the patient's own flora such infections are classified as endogenous. However, sometimes these organisms are carried on the hands of healthcare workers and visitors and may be transferred from one patient to another or transferred to a patient via the environment or equipment shared between patients.

Important strategies to prevent such infections in augmented care setting such as Neonatal Units include maintaining the highest level of hand hygiene, delivering the best device care and ensuring a very high standard of environmental cleanliness and disinfection/sterilisation of equipment used for patient care. Adherence to and compliance of these standards can be audited and the results fed back to directorates and individuals for constant improvements and sustaining best practice.

National surveillance of blood stream infections is conducted by WHAIP. In the All Wales Top Ten blood stream infections (bacteraemia) reports (1/1/2011 to 31/12/2011) *E.coli* was ranked 1st with 59 per 100,000 bed days. http://www.wales.nhs.uk/sites3/page.cfm?orgId=379&pid=13066#z
The highest rates of bacteraemias occur in the those aged below 1yr of age and those above 65yrs of age.

Over the last decade, infections caused by *Escherichia coli* possessing Extended Spectrum Beta-Lactamase, enzymes able to break down treatment antibiotics, penicillins and cephalosporins, have been increasing reported.

Annex C

Extended spectrum beta lactamases (ESBL)

Extended spectrum beta-lactamases are enzymes that break down particular antibiotics, mainly penicillins and cephalosporins, rendering them ineffective against the pathogenic organisms producing them.

ESBLs were first described in the mid-1980s and during the 1990s were mostly found in an organism similar to *E. coli* called Klebsiella. Infections caused by *Klebsiella* species commonly occur in hospitals and often in intensive care units treating the most vulnerable patients.

Until recently, the numbers of patients affected remained small and the problem showed little sign of growing.

However, a new class of ESBL (called CTX-M enzymes) have emerged and these have been widely detected among *E. coli* bacteria.

These ESBL-producing *E. coli* are able to resist antibiotics such as penicillins and cephalosporins and are found most often in urinary tract infections. Organisms producing ESBL may also be resistant to multiple antibiotics limiting the options for treatment. Delays in initiating appropriate and effective treatment and increased mortality are a few of the consequences of such resistance.

Increasingly, ESBLs have been found in the community and hospital settings, but sometimes patients with 'community acquired' infections may have had previous contact with hospitals.

In the United Kingdom, infections caused by ESBL producing organism have been reported in the medical literature and are increasing. Globally, ESBL

producing organisms have been found in many countries. In some countries the prevalence of infection with ESBL producing organisms is higher than others. Individuals who travel to such countries may become colonised and on their return, may have a higher risk of infections caused by these pathogens.

Surveillance studies have demonstrated faecal carriage in people in the community.

Further information on ESBLs can be found by accessing the following links:

- ESBLs – A threat to human and animal health? A Report by the Joint Working Group of Defra Antimicrobial Resistance Coordination (DARC) and the Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI). February 2012
- http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_132534.pdf
- http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_132531
- Investigations into multi-drug resistant ESBL-producing Escherichia coli strains causing Infections in England: September 2005
- http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/ESBLs/
- http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1274090495083

Annex D

Arrangements for the Review

The Review Team

The Review was commenced in March 2012. A Review Team was constructed to include relevant expertise. The members of the Team were:

Dr Bharat Patel	Consultant Medical Microbiologist , Public Health England Microbiology Services Lead for Healthcare Associated Infections in London
Rhys Jones	Head of Investigation
Lisa Bresner	Assistant Investigations Manager

The Review consisted of three stages:

a. Collection and analysis of documents.
b. Fieldwork.
c. Identification of findings, and completion of this report.

Annex E

The Roles and Responsibilities of Healthcare Inspectorate Wales

Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of all healthcare in Wales. HIW's primary focus is on:

- Making a significant contribution to improving the safety and quality of healthcare services in Wales.
- Improving citizens' experience of healthcare in Wales whether as a patient, patient, carer, relative and employee.
- Strengthening the voice of patients and the public in the way health services are reviewed.
- Ensuring that timely, useful, accessible and relevant information about the safety and quality of healthcare in Wales is made available to all.

HIW's core role is to review and inspect NHS and independent healthcare organisations in Wales to provide independent assurance for patients, the public, the Welsh Government and healthcare providers that services are safe and good quality. Services are reviewed against a range of published standards, policies, guidance and regulations. As part of this work HIW will seek to identify and support improvements in services and the actions required to achieve this. If necessary, HIW will undertake special reviews and investigations where there appears to be systematic failures in delivering healthcare services to ensure that rapid improvement and learning takes place. In addition, HIW is the regulator of independent healthcare providers in Wales and is the Local Supervising Authority for the statutory supervision of midwives.

HIW carries out its functions on behalf of Welsh Ministers and, although part of the Welsh Government, protocols have been established to safeguard its operational autonomy. HIW's main functions and responsibilities are drawn from the following legislation:

- Health and Social Care (Community Health and Standards) Act 2003.
- Care Standards Act 2000 and associated regulations.
- Mental Health Act 1983 and the Mental Health Act 2007.
- Statutory Supervision of Midwives as set out in Articles 42 and 43 of the Nursing and Midwifery Order 2001.
- Ionising Radiation (Medical Exposure) Regulations 2000 and Amendment Regulations 2006.

HIW works closely with other inspectorates and regulators in carrying out cross sector reviews in social care, education and criminal justice and in developing more proportionate and co-ordinated approaches to the review and regulation of healthcare in Wales.