The Safe Provision of Maternal & Neonatal Services at Caithness General Hospital



A Public Health Review

Professor Hugo van Woerden Public Health Directorate, NHS Highland November 2016

Introduction

This report has been written in response to a request by the Medical Director of NHS Highland that I lead a public health review of neonatal services in Caithness General Hospital and make recommendations regarding future service delivery. This request was initiated in the wake of the death of a full term baby at Caithness General Hospital on 3 September 2015.

The review has drawn on the expertise of an internal multi-disciplinary team, supplemented by two external reviews. I am very grateful to Dr Brian Magowan, Consultant Obstetrician and Gynaecologist, and Head of Clinical Service NHS Borders, Dr Jane Macdonell, Consultant Paediatrician, NHS Borders, Mrs Nicky Berry, Head of Midwifery, NHS Borders, and Prof. Chris Kelnar, retired Professor of Paediatric Endocrinology, University of Edinburgh, who undertook a review of team working and organisational culture. I am also very grateful to Professor Elizabeth Draper and Professor David Field, both from University of Leicester, who undertook a review of stillbirths and neonatal deaths at Caithness General between September 2010 and August 2015.

I have been ably supported in the review by a team who met weekly to take the work forward including Dr Helen Bryers, Head of Midwifery, Dr Susan Vaughan, Epidemiologist, Angela Watt, Project Midwife and Dr Stephanie Govenden, Consultant Paediatrician. Dr Cameron Stark, Public Health Consultant and Cathy Steer, Head of Health Improvement also contributed for a brief period at the beginning of the review. Dr Lucy Caird, Clinical Lead in Obstetrics & Gynaecology, Raigmore Hospital, Isabel Seaton, Advanced Neonatal Nurse Practitioner, Mairi Stewart, Advanced Neonatal Nurse Practitioner and Alan Richards, Advanced Neonatal Nurse Practitioner, provided expert advice and contributed to reviews of case notes. Jamie Forrester, Health Records Governance & Quality Manager and his staff in Raigmore and Caithness, provided an excellent service retrieving case notes for the reviews. A full list of the staff involved and the wider advisory group is included in the project initiation document, which is included in the report. I am grateful to all of them.

Non-executive board members, Anne Pascoe and Jaci Douglas, have provided useful advice, as have senior members of staff in NHS Highland including Heidi May, Nurse Director, Gill McVicar, Director of Operations, North and West, and Maimie Thompson, Head of Public Relations and Engagement.

We are continuing to work with colleagues in Aberdeen and Stirling Universities to understand the views of women and expectant mothers. This work may be helpful to NHS Highland as it responds to this report and takes the service forward.

It is important that we commend the obstetric and midwifery staff at Caithness General for their dedication and commitment to providing a well respected service for their local community. Staff and patients at the Caithness General have had a period of uncertainty whilst this report was being produced, which I recognise has been difficult to deal with.

I believe that the proposals in this report provide the best possible balance between an easily accessible local service and one that provides the safest possible care for families, mums and babies who are born and live in Caithness and Sutherland.

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18 November 2016

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This report should be referenced as:

van Woerden, H.C., Vaughan, S., Bryers, H., Govenden, S., 2016. The Safe Provision of Maternity & Neonatal Services at Caithness General Hospital: A Public Health Review. Inverness: NHS Highland.

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Executive Summary

Background

This report was commissioned following the death of a full term baby at Caithness General Hospital (CGH) on 3 September 2015. The Medical Director of NHS Highland asked that a fuller investigation of perinatal care (i.e. care in the period before and after the birth of a baby) should be undertaken by the Public Health Directorate, involving external expertise and making recommendations in relation to future service delivery.

A working group (The Technical Review Project team) was set up and five high level objectives were agreed with a wide stakeholder group. These were:

Objective 1: Assess compliance with Expert Group on Acute Maternity Services (EGAMS) exit criteria and local Caithness maternity unit exit criteria for maternal care (antenatal booking, intrapartum, postpartum) & neonatal care

Objective 2: Undertake an externally validated review of perinatal mortality & morbidity

Objective 3: Undertake a review of relevant literature

Objective 4: Undertake an external review of team working and organisational culture

Objective 5: Assess the feasibility of engagement with service users to understand their views using a survey based on health economic principles

A technical review (project) team chaired by the Director of Public Health, and including experts in epidemiology, midwifery and paediatrics met weekly to coordinate the project. A reference group, made up of wider stakeholders (local and national professional experts) were consulted on the approach to be taken and on technical aspects of the review. The review was conducted between February and October 2016.

Description of maternity services in the Highland Council area

CGH is classed as an EGAMS Level 2a facility, based on a categorisation proposed in a 2002 by the Expert Group on Acute Maternity Services (EGAMS). This means that the unit has on-site consultant obstetricians (three full time staff), who provide obstetric care including an out of hours on-call service, midwives and consultant anaesthetics. However, the unit does not have any doctors immediately available who specialise in the treatment of newborn babies and there is no Neonatal Intensive Care Unit. CGH is the only Level 2a facility on the mainland of Scotland. It should be noted that CGH also does not have an Adult Intensive Care Unit, which might be needed for mothers who develop serious complications.

NHS Highland has several midwife-led Community Maternity Units (CMUs) in different rural locations including Dr MacKinnon Memorial Hospital in Broadford and Belford Hospital in Fort William. CMUs are classed as EGAMS Level 1 facilities. They are a common model of care provided in many parts of the UK, and are run by midwives without Consultant Obstetric cover.

Raigmore Hospital is an EGAMS Level 2c facility, with access to a Special Care Baby Unit, Neonatal Intensive Care Unit, Adult Intensive Care Unit, and has staff onsite 24 hours per day who have expertise in the treatment of newborn babies and for mothers who develop serious complications. It is ideally placed to provide the 'hub' in a 'hub and spoke' model for the Highland Region.

Demography

The district of Caithness has a female population aged 15-44 years of around 4,200. This is the main catchment population (Caithness mothers account for 97% of all births at the hospital) for maternity services at CGH. The catchment population is very small compared to other obstetric units across the UK mainland. The small catchment population and therefore the low total number of births per year, is an important consideration when assessing the best type of care for Caithness

mothers and babies in the future. A small mainland catchment population such as this is too small to be served by an obstetric unit with onsite obstetricians

The female population aged 15-44 years in Caithness district has fallen by 13% over the last 14 years.

Therefore, the service in CGH is providing maternity care

"A small mainland catchment population such as this is too small to be served by an obstetric unit with onsite obstetricians."

for fewer women than in the past. Moreover, the population projections estimate a fall of 23% in the female population aged 15-44 years by 2026, from 4,500 to 3,500. Service planning should assume a smaller population of pregnant women in Caithness district who require maternity services in the future. This has implications for the model of service and therefore the number of obstetricians and midwives required in CGH in the future.

The population of Caithness is socio-economically deprived, with twice the proportion living in the lowest fifth (quintile) of the Scottish population as measured by the Scottish Index of Multiple Deprivation (SIMD). Greater degrees of deprivation are expected to be associated with a higher prevalence of obesity, smoking, and other factors that the evidence has shown can lead to pregnancy complications and the birth of babies that require specialist care. Mothers and babies from the Caithness district are slightly more likely than mothers from less deprived areas elsewhere in Highland to require specialist care, which cannot be provided locally, and this seems unlikely to change in the foreseeable future.

Virtually the whole of the Caithness District population lives over two hour's drive time from Raigmore Hospital, Inverness; Dunbeath being the only settlement within this drive time. With almost the whole of the Caithness population living over two hour's drive from Raigmore Hospital, the planning of services should take account of these travel times.

Trends in Number of Births

In 2014/15, 169 babies were born in the maternity unit in CGH, of whom 97% lived in the Caithness district and 3% lived in the Sutherland district. The number of deliveries at CGH is predicted to fall further. In the future, we would expect to see around three births per week at CGH. This number of births would normally be dealt with by midwives. It is difficult to justify

having a team of consultant obstetricians available 24 hours a day in CGH to help give birth to such a small number of births, in addition to a team of midwives. Most mothers can safely have a baby under the care of a midwife, with very few mothers requiring the care of an obstetrician.

"Due to safety considerations, it would not be possible to reverse the falling number of births at CGH, regardless of whether or not obstetricians are available 24 hours a day."

The number of births at CGH has decreased by 30% over

the last 15 years. The proportion of mothers from the Caithness district giving birth at CGH has decreased from 95% around 1990/91 to 61% in 2014/15. Internationally accepted changes to 'best practice' have resulted in an increasing proportion of mothers travelling to Raigmore Hospital to

give birth there. Due to safety considerations, it would not be possible to reverse the falling number of births at CGH, regardless of whether or not obstetricians are available 24 hours a day.

Obstetric Cover

To provide 24 hour a day obstetric care in CGH, NHS Highland has to employ a minimum of three full time obstetricians. The opportunity for obstetricians to practise to full capacity in Caithness is limited by the EGAMS 2a model and by the lack of neonatal and adult intensive care facilities. We

expect to have an average of three births a week in CGH. As most births are normal, each obstetrician could not even expect to deliver one baby per week. This means that obstetric staff have inadequate opportunities to undertake procedures such as induction of labour, instrumental delivery or caesarean section in order to maintain their skills. There is insufficient work in CGH for obstetricians and paediatricians to maintain their skills

and be able to respond to complex cases as well as staff based at Raigmore Hospital. While the Caithness consultants do have regular rotation to Raigmore, there remains the matter of professional isolation and inadequate exposure to complex cases on a day to day basis.

Obstetric Practice and Caesarean Section Rates

Findings from the review show that there are indications that obstetric practice in Caithness is affected by: location; the EGAMS 2a model; population size; distance and travel. There is also evidence that, over a number of years, obstetricians in CGH have erred on the side of intervening rather than allowing normal birth. Since 2005, the rates of elective caesarean sections at CGH

have generally been higher than both the average Scottish rates and rates in the rest of the Highland Council area. In 2014/15, elective caesarean section rates at CGH were higher than in any other hospital in Scotland, which is a matter of potential concern.

UK guidance on 'best practice' indicates that elective caesarean sections should not be carried out before 39 weeks. The proportion of elective caesarean sections carried out at CGH was high, 23% compared to the Scottish average of 14%. This finding was statistically significant. The proportion of these carried out before 39 weeks was also high at 35% compared to 32% at Raigmore Hospital. One would expect the selection of

"Providing obstetric interventions in the absence of specialist paediatric/newborn support results sooner or later in avoidable perinatal deaths: we are putting obstetricians in an impossible situation if we ask them to undertake procedures that deliver babies at high risk of requiring special care in a hospital that cannot provide that care."

low risk women for delivery at CGH to result in a lower, rather than higher, rate of elective caesarean sections. This finding suggests that obstetricians have been over treating patients, unintentionally increasing the risk of harm and in doing so, decreasing the overall quality of care for mothers and babies. The way in which obstetricians reach decisions about patient care can be affected by structural factors around them. These factors can encourage excessive treatment, increasing the risk of harm and unintentionally decreasing the overall quality of care for mothers and babies.

It is well recognised in the literature that the intervention rate is reduced in CMUs. The available evidence indicates that providing obstetric interventions in the absence of specialist

"There is insufficient work in CGH for obstetricians and paediatricians to maintain their skills and be able to respond to complex cases as well as staff based at Raigmore Hospital."

paediatric/newborn support results sooner or later in avoidable perinatal deaths and that we are putting obstetricians in an impossible situation if we ask them to undertake procedures that deliver babies at high risk of requiring special care in a hospital that cannot provide that care.

Transferring mothers from CGH to Raigmore Hospital

It is inevitable that some mothers require to be transferred from CGH to Raigmore Hospital during labour. In the most recent data available, 61% of all women transferred were primigravidae (first time mothers). The predominant reason for transfers during labour (intrapartum transfer) was for pre-term labour (84%).

In September 2015, NHS Highland placed temporary restrictions on the undertaking of a range of higher risk procedures at CGH. Inpatient obstetric activity has subsequently decreased by around 60% when comparing the period before and after September 2015. This corresponds to a reduction from around six births or admissions per week to around three births or admissions per week.

"It is essential that neonatal retrieval services and ambulance services (neither of which are part of NHS Highland), work closely with local systems and staff to ensure rapid access to transport by road or by helicopter when it is required."

Inpatient gynaecology, including surgery, has reduced during the same period but more modestly (34%) and equated to an average of four operations per week in the post September 2015 period.

Outpatient antenatal obstetric activity and gynaecology activity did not change markedly and equated to 3.8 new antenatal obstetric outpatients per week and 6.5 new gynaecology outpatients per week. The number of returning outpatients was 8.5 and 12.6 per week respectively. The current and projected volume of activity does not justify the present consultant workforce in CGH.

There is a 24 hour, 365 day per year neonatal retrieval service in Scotland, which can transport a dedicated team of experts to CGH within a few hours. This service is provided by a network of large hospitals. Pulling in such an expert service should provide a higher quality of care than trying to have experts provided locally who do not see enough cases to maintain specialist expertise.

It is essential that neonatal retrieval services and ambulance services (neither of which are part of NHS Highland), work closely with local systems and staff to ensure rapid access to transport by road or by helicopter when it is required.

Literature Review

A literature review was undertaken to inform the review on the risks to mothers and new born babies associated with elective caesarean section and the risk associated with mothers giving birth for the first time; both procedures had been suspended at CGH after the occurrence of the neonatal death in September 2015.

Risks to mothers associated with caesarean section

Mothers having an elective caesarean section have an increased risk of complications. The risks range from difficulties with breastfeeding and infections, to the need for treatment in an Intensive Care Unit, for example, due to major post-partum haemorrhage (heavy bleeding after birth). Around 6.4 mothers per 1,000 giving birth will require the use of intensive care facilities. This is an almost two fold increase compared to a rate of intensive care use of 3.9 mothers per 1,000 planned vaginal births. Factors associated with a reduced risk from elective caesarean sections

were: (i) births at or after 39 weeks, (ii) no previous caesarean section, (iii) no general anaesthesia, (iv) no breech presentation.

Elective caesarean sections before 39 weeks of pregnancy are associated with an increased risk of respiratory problems in the newborn baby. The National Institute of Health and Care Excellence (NICE) guidance states that elective caesarean section should not be undertaken before a mother is 39 weeks pregnant. The exception is where the baby is in the breech position, when an elective caesarean section significantly reduces the risk to the baby. However, the procedure is still associated with an increased risk to the mother. This finding raises questions as to why elective caesarean sections were being undertaken in CGH before 39 weeks.

There is a clear recommendation by the National Institute for Health and Care Excellence (NICE) that paediatric support, in terms of practitioners appropriately skilled in resuscitation, should be present when caesarean sections are performed under general anaesthetic or when foetal distress is evident. These procedures should not be undertaken at CGH in the future, as local staff do not have adequate neonatal expertise and nor would they be able to maintain such skills due to the small numbers. This too has implications for the future design of the local maternity services.

Risks to first time mothers giving birth in Caithness

First time mothers giving birth in Consultant–led Units (CLUs) have higher rates of interventions and adverse outcomes (as do their babies, although to a lesser extent), compared to those giving birth in a midwife-led CMU. This fact supports local midwife led CMUs for appropriately selected women.

The literature review sought to answer the question as to whether the suspension of the delivery of first time mothers (primigravidae) at CGH should be reversed.

The literature review identified that around 25% of first time mothers would be classed as 'high risk' and would require 'step-up' care. In the case of mothers from Caithness, this would mean that a quarter of first time mothers would be booked to have their baby at Raigmore Hospital. If the remaining three quarters were booked to deliver at a CMU in Caithness, we would expect over a third to require transfer to Raigmore during delivery because of emerging complications. This contrasts with women who have had one or more previous babies, where we would expect 5% to need transfer to Raigmore Hospital.

Assuming that the recommendations of this report are accepted, redesign of services at CGH to provide a CMU will result in more women travelling to Raigmore Hospital, but this should provide these mothers and their babies with safer outcomes. Women classed as 'low risk' who give birth in a CMU based at CGH would expect to have fewer unnecessary interventions than is the case in the current

"Although the introduction of a CMU at CGH would increase maternal transfers, it would decrease neonatal transfers and provide further reduction in neonatal deaths."

EGAMS 2a unit. Using models based on RCOG and on existing local exit criteria, the adoption of a CMU may be expected to increase the current annual Raigmore birth workload of 2,000 by 1-3%.

In summary, the literature review highlights the additional risks that expectant mothers and clinicians must consider when making a choice over how and where to give birth. First time mothers, older women, and those women who live in an area of greater deprivation will face the highest risk of complications for themselves and their baby, regardless of the mode of delivery. In the context of women who give birth in Caithness, an increased risk of complications leads to an

"Elective caesarean sections are associated with risks that cannot safely be managed at CGH."

increased risk of being transferred after labour has started to a larger maternity unit, such as Raigmore, that is equipped with additional staff and facilities to provide specialist support to mothers and babies.

In conclusion:

- The literature review does not support the reinstatement of elective caesarean sections at CGH, as these procedures are associated with risks that cannot safely be managed in that context.
- The available literature does suggest that the suspension of primigravidae births at CGH could be lifted if the risks were reduced by appropriate risk assessment as is the case for first-time births taking place in CMUs.

Case Note Review Methods

A review of case notes was undertaken using several different approaches, which were designed to give an overall view of maternal and neonatal care and to identify cases from which lessons could be drawn. The review was undertaken in stages and designed to meet objectives one and two above. The sampling frame for each aspect of the review is summarised below.

To meet objective one, we assessed a sample of 60 of the 163 births occurring at CGH in the 12 month period between September 2014 and August 2015. Cases were assessed against the exit/transfer criteria in place at CGH prior to September 2015.

To meet objective two, we undertook a review of maternal transfers, neonatal transfers and births where the baby had a low Apgar score. Babies with low Apgar scores five minutes after birth are in a critical condition and require skilled resuscitation. We wanted to assess how well resuscitation had been managed in the most complex cases. Relevant cases were drawn from the five year period between September 2010 and August 2015. A proforma was used to assess the quality of care. All the case records identified were reviewed by multidisciplinary teams of reviewers comprising a Paediatrician, an Obstetrician, a Midwife and Advanced Neonatal Nurse Practitioners (ANNP). The membership of the teams was such that there was both NHS Highland and external representation in the assessment of each set of case notes.

All cases in which concerns were identified were collated for a second stage review by a panel. The panel, chaired by the Director of Public Health, included an Obstetrician, two senior Midwives, a Paediatrician and an Advanced Neonatal Nurse Practitioner. A proforma was used to review the 20 cases that had been identified from the first stage reviews. Each case review considered three key questions: i) What should have been done to minimise the risk to the mother and/or baby? ii) What needs to be done to avoid it happening in the future? iii) If CGH had been a midwife-led unit, would the problem have arisen?

A second piece of work was undertaken to meet objective two. The review team commissioned an external review of stillbirths and deaths around the time of birth (perinatal mortality). The external team were asked to look at perinatal cases identified for the five year period between September 2010 and September 2015. These cases were sent to Professor Draper and her team at the University of Leicester who carried out this work between May to September 2016.

Results of the case note review

The case note reviews were conducted to assess whether clinical decisions were being made in line with guidelines that were in place prior to September 2015. Together, the reviews considered 144 case notes, and from these identified 20 cases (16%), where the clinical care raised concerns. These cases were subject to a second panel review, which confirmed that 15 of the 20 cases reviewed (75%) had areas where practice was sub-optimal and where there was significant opportunity for improvement.

The main areas identified for improvement and where care was suboptimal were: treatment and management that was out with best practice guidelines; apparent lack of awareness of the neonatal implications of the management plan; opportunities for earlier transfer to Raigmore Maternity Unit; opportunities for greater teamwork and leadership; and appearing to temporise or hold onto cases when this appeared to be suboptimal.

A case study is provided as an example in the box below.

Case study (details have been modified to preserve anonymity)

A pregnant woman was admitted to CGH some weeks before her baby was due to be born with symptoms of a common but serious condition that occurs in the later part of pregnancy. She was monitored for some time, but developed features that suggested that her condition was deteriorating. She was eventually transferred to a better equipped hospital where additional treatment was initiated.

Commentary

Although there was no adverse outcome for the mother or baby, the review panel were of the view that optimal treatment would have involved earlier transfer to a better equipped hospital. There was some risk that if the condition had deteriorated further, the mother or the baby could have experienced avoidable harm and in the worst case scenario, delay in treatment both could have resulted in the death of both mother and baby.

The pattern that emerges suggests that there are structural issues associated with the EGAMS 2a model, which perhaps explains why it has rarely been used in the UK. The potential risks

associated with an EGAMS 2a model merit further discussion at a national level.

There is clear evidence from published literature that delivery of low risk mothers in a CMU reduced low value interventions that are associated with unnecessary risk. The review panel were therefore asked to assess whether they believed that the issues identified at CGH were "The review panel concluded that 67% of problems with care identified in the audit of case notes would probably have been avoided if CGH had been operating as a midwife-led CMU."

"more likely, equally likely, possible, or unlikely" to have occurred if care had been provided at a CMU. The review panel concluded that 67% of problems with care identified in the audit of case notes would probably have been avoided if CGH had been operating as a midwife-led CMU. This finding supports the conclusion that low risk mothers would receive safer care, and care was more appropriate for their needs, if maternity services at CGH were based on a CMU.

The review also identified the importance of maintaining and updating skills and competencies and improving communication between Raigmore and CGH, so that expert advice is obtained as early as possible when assessing potential problems.

External visit and review

An external team was invited to Caithness General Hospital and Raigmore Hospital to meet staff

and consider how systems, processes and teamwork could best be designed to ensure safe care for mothers and newborn babies.

"The external review team recommended that CGH should be reconfigured as a midwife-led CMU."

The external review team concluded that, "Given the apparently insuperable problem of ensuring the local

availability of safe neonatal cover, it was the unanimous clinical view of this Review Team that the maternity service in Caithness should be reconfigured as a CMU."

The team also made the following suggestions to facilitate the transition to a CMU:

- "A common theme from both CGH and Raigmore was the lack of facilities for mothers waiting to go into labour in Raigmore. This could be considerably improved by a new comfortable, family-centred, facility in Raigmore.
- Transport delays could be improved with the purchase of a transport pod to allow babies to be transferred to Raigmore by this method, although this would require defined criteria for transport and a sufficiently trained staff member at CGH to accompany the baby.
- Some increased resource might be required in Raigmore to support the increased numbers of deliveries.
- Consideration will need to be given around the delivery of gynaecology services at CGH and the implications for service delivery at Raigmore."

External independent enquiry

Professor Draper and her colleagues considered the case notes of two stillbirths and three neonatal deaths using a standardised system of documentation to identify 'good' or 'poor' care and

whether or not this affected the outcome. The review identified two cases that were classed as Grade 3, that is, "Sub-optimal care in which different management would reasonably be expected to have made a difference to the outcome". There is therefore evidence from this external review to suggest that at least two of the five perinatal deaths (stillbirths or neonatal deaths) which occurred over the past five years were potentially avoidable.

"There is evidence from this external review to suggest that at least two of the five perinatal deaths (stillbirths or neonatal deaths) which occurred over the past five years were potentially avoidable."

The review concludes by saying, "In relation to obstetric and midwifery care, the service at Caithness appears (in relation to these cases) to operate to a satisfactory standard. However, the geography and the nature of the staff available set limits on what can be provided without transfer.

It is important that these limitations are made clear to women who book at this unit."

Models of care

The review team undertook an option appraisal of different models of care. They concluded that a 'hub and

"A 'hub and spoke' model is best placed to provide care across Highland Region for remote and rural mothers and babies, including those in Caithness and Sutherland." spoke' model is best placed to provide care across Highland Region for remote and rural mothers and babies, including those in Caithness and Sutherland. We also need to learn the lessons from international best practice. For example, there is an opportunity to learn from Scandinavian countries, which also have remote and rural areas but have achieved very low levels of maternal and neonatal complications and deaths.

Conclusions

This review has considered maternity and neonatal services in Caithness from several perspectives. The internal review concluded that the population of Caithness and Sutherland would best be served by a CMU in CGH. This view was based on several strands of evidence including demographic trends, the profile of clinical activity, the literature review, and an analysis of care notes. The external review team also recommended transfer of the unit at CGH to a CMU.

Staff in the CGH maternity unit are dedicated and hard working and this report is not intended to be a direct criticism of the staff. We believe that there are structural issues with the current model, which mean that suboptimal care is likely to occur. This constitutes a safety issue and recommended changes are based on that understanding.

With regards access to care and accommodation for women and families in Raigmore, the external review identified that travel to Raigmore and issues with limited accommodation for women and their families had an impact on care, particularly when combined with psycho-social factors and women in vulnerable situations. The external review report suggested that homely facilities in or near Raigmore Hospital could ease the social impact of changes to service configuration.

In order that women can make an informed choice about their care and place of birth, the external reviews recognised that women should be given clear information about the level of service available in Caithness maternity and the limitations with regards neonatal care and adult high dependency care.

Recommendations

This report makes two recommendations:

1. Caithness maternity unit should become a midwife-led CMU in line with the model of maternal and neonatal care in other parts of NHS Highland. This change is designed to improve the safety of both neonatal and intrapartum care for the population of Caithness and Sutherland.

2. Strengthen the hub and spoke model of maternal and neonatal care across the North Highland Health and Social Care Partnership (HHSCP). This approach would strengthen Raigmore as a hub, providing 24 hour per day obstetric, midwifery and neonatal support to all the CMUs and community midwifery teams across the HHSCP. Obstetric, midwifery and neonatal staff based at Raigmore Hospital would support all the spokes in the model, including Caithness and Sutherland.

This model will require additional leadership by clinical and managerial staff, greater use of communication technology, ready access to homely accommodation for mothers and families who may have to stay near Raigmore hospital, and closer liaison with ambulance services and neonatal retrieval services to ensure a seamless pathway of care.

1 Background

Following the neonatal death of a full term baby at Caithness General Hospital on the 3rd September 2015, a significant adverse event review (SAER) was instigated in order to understand the events that led up to this tragic outcome. The baby died in Caithness approximately 40 hours after birth. The cause of death was identified at post-mortem as overwhelming infection. The SAER made recommendations to gather further information regarding the safety of neonatal care in Caithness General Hospital. Recommendation 7 states: that "A public health led review of the service, supported by expertise external to NHS Highland must be undertaken to inform the future configuration of obstetric services in Caithness General Hospital".

A formal letter from the Medical Director laid out the following requirements: To conduct a review of the safety of neonatal care for babies delivered at the Caithness Maternity Unit; to make recommendations as to how any identified risks might be mitigated taking account of the overall available resources; the arrangements for neonatal surveillance and escalation; the provision of neonatal medical paediatric advice and support; the delivery policy of the Maternity Unit as a whole, given that it is evident that maternal case mix is a potential significant determinant of overall neonatal risk. This report is the result of that recommendation and of discussions with NHS Highland's Medical Director and Chief Executive.

A project initiation document was developed and agreed with the Medical Director and a working group (technical review team) chaired by the Director of Public Health was set up to take the project forward. A stakeholder group consisting of a wider range of internal and external experts was consulted with in relation to technical approaches and issues. The membership of both groups is listed in an appendix (10.1).

1.1 Project Aim

Five objectives were formulated to address the aims of the project:

1. Assess compliance with EGAMS and Caithness maternity transfer (exit) criteria from antenatal booking, to intrapartum, neonatal and postpartum care.

2. Undertake an externally validated review of perinatal mortality and morbidity.

3. Undertake a review of relevant literature.

4. Undertake a review of team working and organisational culture.

5. Assess the feasibility of engagement with service users to understand their views using a survey based on health economic principles.

1.2 Current maternity services at Caithness General Hospital

The maternity service in Caithness are part of the NHS Highland maternity & neonatal service. The model of care is described in the NHS Highland Maternity and Neonatal Services Strategy (2015) and is provided in line with The Refreshed Framework for Maternity Care in Scotland (SG 2011).

The service is provided in a variety of locations and at various levels of care.

Maternity services in Scotland are categorised on the basis of a 2002 report by the Expert Group on Acute Maternity Services (EGAMS). In Caithness, there is an EGAMS Level 2a maternity unit

within Caithness General Hospital (CGH). This unit has continuous access to locally based obstetricians and midwives but no paediatricians, advanced neonatal nurse practitioners or on-site adult high/intensive care facilities. This type of arrangement is unique in mainland Scotland. Care that is more complex is provided in Raigmore Maternity and Neonatal Units within Raigmore Hospital, Inverness. This unit has more extensive facilities including an adult Intensive Care Unit, a Special Care Baby Unit, and associated staff who are trained to manage women with higher risk pregnancies. The Raigmore maternity unit is classed as an EGAMS level 2c maternity facility. NHS Highland has seven midwife-led Community Maternity Units (CMUs). Two of these are adjacent to a Rural General Hospital (Oban and Fort William). These are classed as EGAMS Level 1c facilities. There are also five CMUs adjacent to a Community hospital (Campbeltown, Isle of Bute, Dunoon, Lochgilphead and Broadford in Skye). These are classed as EGAMS Level 1b maternity facilities.

These maternity units are run by midwives and the care for all pregnant women and postnatal mothers is co-ordinated through these midwifery teams. The CMUs have visiting consultants providing obstetrics and gynaecology clinics. All the CMUs provide birth facilities for low risk mothers. In addition to the CMUs, there are community midwifery teams, which provide continuous antenatal and post-natal care for mothers and babies and a small number of homebirths. This model is used across the UK and other developed countries.

The midwives in the CMUs provide intrapartum care for women classed as being at 'low risk' of complications. Women at 'high risk' are booked for intrapartum care in Raigmore (or Royal Alexandra Hospital in Paisley for Argyll and Bute residents). The CMUs can provide local assessment of high risk women prior to transfer to Raigmore. Transfer to Raigmore is normally triaged through Raigmore and advice on how to travel given (ambulance or own transport depending on risk assessment). In other cases, women with high risk complications are asked to live in the Inverness area if, for instance, daily monitoring of mother and foetal wellbeing is required. At other times, women need to be admitted to the maternity unit in Raigmore.

If a woman who is classed as being at 'high risk' presents to CGH in the later stages of labour, a decision has to be made as to whether it is safer to keep the woman in Caithness rather than risk the baby being born on the way to Raigmore maternity unit. Similarly, women who develop complications in labour are transferred to Raigmore, unless labour is so advanced that this would pose an undue risk of delivery before arrival. When babies are born prematurely or are unwell at birth and in the early neonatal period, staff in Caithness will liaise with the SCBU in Raigmore the North of Scotland Neonatal Retrieval Team are called to transfer the neonate. The team is based in Dundee and transfer times are long; it often takes 8-12 hours from the request for such a transfer to the arrival of the neonatal team in Caithness and even longer to then transfer the mother or baby in a Level 2c or 3 maternity units with a NICU (Neonatal Intensive Care Unit).



Map 1: Maternity services locations in NHS Highland and drive times to Raigmore Hospital

Nearly all (97%) of the births at Caithness General are amongst women resident in the district of Caithness and, as can be seen in Map, almost the whole of this catchment population is over two hour's drive from Raigmore Hospital. Appropriate risk assessment and decision making is vital in this situation, as it is in all other remote areas of NHS Highland. Decisions on time and when to transfer are taken earlier from remote settings in order to factor in journey time and at times, weather conditions.

Conclusion: Given the time required to travel from CGH to Raigmore Hospital, it is better for mothers or babies who may require specialist care to travel earlier rather than a later.

1.3 Demographic characteristics

The female population (15-44 years) is most relevant to the catchment of maternity services at CGH. This population has decreased by 13% over the last fourteen years (from 4,836 in 2001 to 4,200 in 2014) amongst the population of the Caithness District with most of the decrease occurring since 2009 (Figure 1).





Data source: National Records of Scotland; 2001 to 2014 Small Area Population estimates based on 2011 data zones

Projections of the maternity population in Caithness District estimate a further decrease of numbers in 2026 by 1,000 (4,200 in 2012 to 3,500 in 2026; see figure 2).

Conclusion: Figure 1 suggests that if past trends continue, there will be fewer women in the Caithness area over the coming decade.

Figure 2: 2012-based population projections in the female population aged 15-44 years in the catchment for Caithness General Hospital



Data source: National Records of Scotland: 2012-based population projections for sub-council areas by sex and single year of age, 2012-2037

There has been some inward migration from Eastern European countries (mainly Poland). However, this is unlikely to change the above projections significantly.

Conclusion: Figure 2 projects a decreasing female population in the Caithness area over the coming decade. We would expect this to mean that fewer women will get pregnant and require maternity services.

Deprivation data is shown in figure 3. The district of Caithness has twice the proportion of the maternity population living in the most deprived quintile than that of Highland Region overall, 21% versus 10%.

Figure 3: Maternity population around Caithness General Hospital by quintile of deprivation: Based on national 2012 ranking and 2014 small area population estimates



Data source: Scottish Government SIMD12 by data zone and NRS small area population estimates 2014

The deprivation in the Caithness area represents significant underlying need in the population, which would be expected to have a slightly higher rate of pregnant women classed as being at higher risk of complications during pregnancy.

Conclusion: Mothers living in Caithness are more likely than average to require specials care that cannot be provided locally. It is probably better to ask these women to travel to Raigmore at an early stage before problems arise rather than wait until problems occur.

The number of births at CGH has decreased by almost 30% over the last fifteen years from 236 in 2000/01 to 169 in 2014/15 (figure 4). The births at CGH were predominantly from amongst women living in the Caithness District (97%) with the remaining 3% of the births from mothers resident in the Sutherland district (figure 4).





Data source: GROS births and NRS small area population geographies, NHS Highland

Analysis of live births amongst the population of the district of Caithness by hospital of birth shows that only 61% of them occur at CGH (figure 5). Most of the remainder (34%) occurs at Raigmore Hospital. The proportion of births amongst Caithness mothers occurring at CGH has decreased from 95% in the early 1990s with a concomitant increased proportion occurring at Raigmore hospital (figure 5). The increased use of Raigmore Hospital for births amongst the population of the district of Caithness is in the context of relatively unchanging numbers of total births year to year over the last ten years (figure 5).

Figure 5: Numbers of live births to women resident in the district of Caithness by hospital of birth



Data source: GROS births and NRS small area population geographies, NHS Highland

Only 8% of the births amongst women resident in the district of Sutherland occur at CGH whilst in the early 1990s, over 20% occurred there.

Conclusion: Figures 4 and 5 suggest that service planning should assume a smaller number of births in Caithness General in the future.

Conclusion: The low number of births (around three per week), make it almost impossible for an obstetrician to maintain their skills.

The most recent profile of location of births by district of residence across the Highland Council area is provided by Map 2.



Map 2: Proportions of births by hospital of delivery for residents of each district in the Highland Council area

Although the maternity population itself is decreasing, the numbers of live births according to figure 5 (all hospital line) has been relatively stable over the last five years. This indicates that the general fertility rate had slightly increased over the same period. This is shown in figure 6, where, on average, there was a 9% increase between the years 2005-2009 and 2010-2015 in fertility rates

in to the Caithness population. This also applied to Sutherland (8% increase) and to the Highland Council area as a whole (2% increase).

Figure 6: General Fertility rates of the populations of Caithness, Sutherland and Highland Health and Social Care Partnership



Data source: GROS births and NRS small area population geographies, NHS Highland

It is unlikely that the fertility rate will rise further, as the rise observed to date is most likely reflective of previous immigration by a younger population.

Conclusion: In the context of this report, the overall impact of a rise in fertility rate is small. This finding is consistent with the conclusion that future service planning should be based on an assumption that there will be fewer births to women living in the Caithness area in the future.

1.4 Modes of delivery

Births are normally classified as spontaneous vaginal delivery (SVD), vaginal delivery of a baby in the breech position, instrumental delivery by an obstetrician (includes vacuum delivery and forceps delivery), elective caesarean section and emergency caesarean section. The proportion of births by each mode of delivery is shown in figure 7. During each of the financial years between April 2005 and March 2015, the rate of spontaneous births at CGH was similar to that at Raigmore Hospital, and was actually lower during 2009/10 (figure 7 below).

This means that a high proportion of births involved the intervention of an obstetrician. This would not be expected in a small hospital such as CGH, as one would expect to have effective selection of low risk births in a remote maternity unit, which would lead to a higher proportion of spontaneous vaginal deliveries.

Conclusion: In comparison with Raigmore, CGH has a very high rate of intervention in an already selected low risk group of mothers. The questions raised by this are whether this is due to differences in clinical practice and decision making. Patient choices will also play a role in these figures, nevertheless the data in figure 7 suggests that there are differences in clinical between Caithness and Raigmore.



Figure 7: Percentage of births at Raigmore and Caithness General hospitals during each of the years, 2004/05, 2009/10 and 2014/15^p by mode of delivery

NB: 2015p= provisional data for 2014/15; Source: ISD: Births in Scottish Hospitals; Publication date 24th November 2015, data from table 4.

Another measure of quality of care is induction of labour, which is included in the overall rates on intervention. An obstetrician may decide to induce labour when there is clinical reason that the ongoing pregnancy poses risks to the mother or baby. One would expect a low rate of induction in a small unit with no neonatal service, which should primarily be dealing with women at low risk. The rates of induction (not shown in figure 7 above as they are not mutually exclusive from the other modes of delivery), were higher in CGH than in Raigmore during 2004/05 (27.8% versus 25.5%), not recorded in 2009/10 and lower in 2014/15 (12.2% versus 30.5%).

Conclusion: The finding of a high level of induction of labour in Caithness General is unexpected and raises questions in relation to the overall intervention rate in an already screened maternity population. The findings are consistent with a sub-optimal service.

As noted in figure 7 above, the rates of elective caesarean sections in CGH have increased over the three years so that they accounted for over 20% of all deliveries in 2014/15.

Figure 8: Elective caesarean section rates in Scottish Hospitals pertaining to the financial year end 2015



NB: 2015p= provisional data for 2014/15; Source: ISD: Births in Scottish Hospitals; Publication date 24th November 2015, data from table 4

Figure 8 indicates that CGH had the highest caesarean section rate in Scotland in 2014/15. Similar data based on district of residence is shown below (figure 9).





Data source: SMR02; *graph shows 95% confidence intervals

Figure 9 indicates that the highest elective caesarean section rates in the Highland Council area are observed amongst the population of Caithness District.

Conclusion: The rate of elective caesarean sections in CGH is the highest across all hospitals in Scotland and higher than that of Raigmore Hospital. The rate is statistically higher than the national average (figure 8). This finding is unexpected, as one would expect selection of low risk women for delivery in Caithness Hospital to result in a lower, rather than higher, rate of elective caesarean sections. The findings are consistent with a sub-optimal service.

There is some evidence that there are additional risks to the baby of respiratory complications requiring neonatal paediatric intervention if elective caesarean sections are undertaken before 39 week gestation NICE (2004). It would not be best practice to undertake such elective caesarean sections in a context where there was no onsite neonatal paediatric support. We would therefore not expect to see elective caesarean sections being undertaken in the Caithness Hospital before 39 weeks gestation.

Analysis of SMR02 demonstrated a higher proportion of elective caesarean sections carried out before 39 weeks of gestation at CGH than at Raigmore Hospital. The numbers and rates over the last 10 years show a relatively high rate where in 2015, it was 35.1% compared to 32.4% at Raigmore (figures 10 and 11).



Figure 10: Numbers of elective caesarean sections carried out at Caithness General Hospital each year over a ten year period (Financial Year ending 2006-2015)

Source: Analysis of SMR02 data by Public Health Intelligence and Knowledge Team, NHS Highland, p = provisional data

Figure 11: The proportion of elective caesarean sections carried out at less than 39 weeks of gestation at Raigmore and Caithness General Hospitals each year over a ten year period (FYE 2006-2015)



Source: Analysis of SMR02 data by Public Health Intelligence and Knowledge Team, NHS Highland, p = provisional data

There are several instances in the previous data that are outside best practice. It is conceivable that the underlying cause for such practice may be related to structural factors. The opportunity for obstetricians to practise to full capacity in Caithness is limited by the EGAMS 2a model and the lack of neonatal and adult intensive care facilities. This means that obstetric staff have few opportunities to undertake procedures such as induction of labour, instrumental delivery or caesarean section and other opportunities to maintain skills. In some instances, there is evidence that this has led to some procedures that are of marginal benefit to the patient.

Obstetric staff based at CGH are offered the opportunity to undertake regular rotations in Raigmore Hospital to help maintain skills, but it can be argued that this is inadequate to ensure all skills are fully maintained.

Conclusion: The high rate of elective caesarean section identified in figures 10 and 11 are consistent with a suboptimal service. Given the available evidence, this report recommends that caesarean sections should not be offered to women as a standard delivery option at CGH.

Conclusion: The available data suggests that the population and therefore the birth rate in CGH are so small that the maternity unit cannot generate enough work to allow obstetricians to maintain their skills. Therefore, a new pattern of working will be required in order to maintain both optimal patient safety and the competencies of the obstetric workforce.

In previous decades, a single handed specialist such as an obstetrician, in a small rural hospital, who was on call 24 hours a day for most of the year, would have seen a significant number of cases and therefore would have been able to maintain their skills. With modern rotas, this is much

more difficult to achieve. In the past it was also possible to find GPs who had training in neonatal care and who were willing to be on call 24 hours per day for most of the year to support a small hospital with neonatal resuscitation, but staff such as these are no longer available and where previously there was a certain long term stability in terms of the experience of staff who could be relied upon in cases of concerns, this is no longer the case.

Conclusion: The model of obstetric care in Caithness is not compatible with modern professional requirements.

Further evidence surrounding the safety of caesarean sections and the risks associated with primigravidae (a woman who is pregnant for the first time) is presented in the literature review section of this report.

1.5 Transfers of first time mothers from Caithness General Hospital

A key task for this review was to consider the quality of decision making in relation to the transfer of mothers and babies from CGH to Raigmore Hospital or other obstetric units. It was therefore necessary to identify the sampling frame of women who had been transferred from CGH. It is harder to predict the risk for women who are pregnant for the first time. For that reason, we were particularly interested in focusing on this group.

Analysis of SMR02 allowed assignation of parity to the ninety four records of maternal transfers logged by staff in CGH in a locally held log (see review methods section 3). Of these, 61% (n = 56) were primigravidae. This is a higher rate than the proportion of all maternities, which during 2014/15 was 46% (ISD Births in Scottish Hospitals, 2015). Transferred primigravidae women were identified as either, 'transfers in the antenatal period' or 'intrapartum transfers' as per the box below.



Figure 12: Identified primigravidae maternal transfers

The reason for transfer was then extracted from the Caithness log providing the following profiles for (i) the antenatal transfers and (ii) the intrapartum transfers (table 1).

	Stage at tra	Insfer
Reason for	Antenatal	Intrapartum
transfer	number (%)	number (%)
Other	2 (5%)	0
Woman unwell	2 (5%)	0
АРН	2 (5%)	0
Epidural	2 (5%)	0
Foetus	4 (11%)	0
SRM > 37 wk	4 (11%)	3 (16%)
PTL < 37 wk	5 (14%)	16 (84%)
SRM < 37 wk	6 (16%)	0
Pre-eclampsia	10 (27%)	0
All above	37 (100%)	19 (100%)

Table 1: Reasons for maternal transfers of primigravidae by stage of transfer

Source: Parity identified from SMR02 data, and reason from Caithness log

The most common reason for intrapartum transfer was by far pre-term labour (84%), with the remainder all due to spontaneous rupture of membranes at term. The most common reason for transfer in the antenatal period was due to pre-eclampsia (27%). These findings were in line with what we expected to observe.





Source: Analysis of Caithness logged transfer records to which parity from SMR02 records were assigned

In the antenatal period, 38% of mothers used their own transport to travel to Raigmore Hospital, whereas no mothers used their own transport during intrapartum transfer (figure 12). One third of transfers in the intrapartum period were by air. These proportions were broadly in line with what we expected to observe. They may be useful for future service planning of services across NHS Highland.

1.6 Perinatal mortality

A key priority for this review was to consider the management of cases where there had been a death around the time of birth. A perinatal death refers to a stillbirth or early neonatal death. A stillbirth is a baby delivered at or after 24 ⁺⁰ weeks gestational age showing no signs of life. An early neonatal death is a live born baby born at 20⁺⁰ weeks gestational age or later, who died before seven completed days after birth. Stillbirth rates and perinatal death rates are based on a denominator comprising of the sum of live and still births. Perinatal deaths were taken from the 'National Records of Scotland' (NRS) weekly vital event recording of births, deaths and stillbirths.

An *a priori* decision was made that perinatal deaths in the preceding five years would be sent for review by an external panel. The number of perinatal deaths, for an area with as few births per year as Caithness, is likely to be small, as these deaths are rare, and there will be more deaths in some years than others due simply to the natural variability of such events. Table 2 summarises the annual number of stillbirths and early neonatal deaths relating to the population of Caithness District.

	Year of death																			
	<i>\</i> 0	³⁶ , 95	5 ¹ ,9	3° ,0	³⁹ 40	00 20	o' 20	⁵² 20	⁵³ 26	⁰⁴ 20	⁵⁵ 25	²⁶ 26	⁵¹ 26	³⁸ 29	³⁹ 20	10 20	N 20	² 20	¹ 2 20	14 20
Stillbirtbs	2	5	1	3	0	0	1	0	0	0	2	5	1	3	0	2	0	1	0	1
Early Neonatal deaths	1	0	1	1	1	2	1	0	1	0	0	1	1	1	0	2	1	1	1	1
Perinatal deaths	3	5	2	4	1	2	2	0	1	0	2	6	2	4	0	4	1	2	1	2

Table 2: Stillbirths and early neonatal deaths in the Caithness District* by calendar year

*Based on maternal postcode of residence; p = provisional data

Longitudinal control charts are provided in figures 13 and 14 for rates of stillbirths and perinatal deaths respectively, to identify any points out with random variation. The charts show no period in which the upper control limit has been exceeded. Such an instance would prompt immediate cause for enquiry.



Figure 14: Control chart of Caithness stillbirths based on the Scottish mean rate

NB: the lower limits run below the bottom of the chart area. Lower and upper warning limits (LWL and UWL) are set at 2 s.d. and lower and upper control limits (LCL and UCL), at 3 s.d.

Figure 15: Control chart of Caithness perinatal mortality based on the Scottish mean rate



NB: the lower limits run below the bottom of the chart area. Lower and upper warning limits (LWL and UWL) are set at 2 s.d. and lower and upper control limits (LCL and UCL), at 3 s.d.

There were seven antepartum stillbirths to mothers resident in Caithness and Sutherland during an 11 month period from 1st August 2006 to 30th June 2007 (table 2 above). At the time, there was concern that this represented a higher rate of stillbirth than would be expected. Internal and external review revealed no consistent explanatory factors (SPCERH 2007¹).

Perinatal data can be presented by hospital rather than by area of residence. Table 3 highlights that on average there were less than two such events a year at CGH. Four deaths were identified in the period between the 1st of September 2010 and the 31st of August 2015 for external review as part of the current process.

¹ SPCERH, 2007. Peer Review of stillbirths in Caithness and Sutherland. Review Report for NHS Highland.

Table 3: Stillbirths, early neonatal deaths and perinatal death at Caithness General Hospital by calendar year

									Y	ear o	f dea	th								
	20	°,	5 ¹ ,0	°,	»° 4	³⁰ 20	» ² 20	³² 20	2 ² 20	⁰⁴ 20	1 ⁵⁵ 10	26 ag	⁵¹ 25	28 P	» 2º	10 20	1 20	² 20	N ² 20	14 201
Stillbirths	2	1	0	2	0	0	1	0	0	0	2	4	1	2	0	1	0	1	0	0
Early Neonatal deaths	0	0	1	1	0	1	0	0	1	0	0	0	1	0	0	1	0	0	1	1
Perinatal deaths	2	1	1	3	0	1	1	0	1	0	2	4	2	2	0	2	0	1	1	1

p = provisional data

1.7 Maternal mortality

Maternal deaths are extremely rare events. Since 2014, the surveillance of maternal deaths in Scotland has been reported by MBBRACE-UK as part of UK wide monitoring². The reporting includes the deaths of women during or after pregnancy and relies on notification from the unit in which the death occurred in routine administrative data sets.

To ascertain retrospectively whether any maternal deaths could be linked to CGH, we examined records from the National Records of Scotland for registered deaths of any women in which pregnancy or pregnancy-specific cause was recorded. In addition, we explored the national SMR02 maternity data set to ascertain if any women had been discharged deceased from the location. A single death was recorded in this source at CGH over the period since 1996. The NRS data recorded the death but did not list a code related to pregnancy. The death happened a number of years before the period of the current review i.e. pre-2010 in 2007. A Serious Untoward Incident (SUI) meeting was held the next day, which instigated a Critical Incident Review Process, the outcome of which was reported locally.

Summary of critical events

A summary of perinatal and maternal deaths occurring at Caithness General Hospital that have been associated with a Significant Adverse Event Review or its historical equivalent, are summarised in figure 15.

² MBBRACE-UK: <u>https://www.npeu.ox.ac.uk/mbrrace-uk</u> [Accessed July 2016]



Figure 16: Perinatal and maternal deaths occurring at Caithness General Hospital from 1996 to 2015 with type of review

Source: NRS registrations and SMR02

SAER= Significant Adverse Event Review; SUI = Serious Untoward Incident; CIR = Critical Incident Review

1.8 Obstetrics and Gynaecology outpatient and inpatient activity

One task required of the review was to make recommendations in relation to future service delivery in CGH. To do this we wanted to determine the activity levels at the hospital. As a result, the activity by calendar year quarter for the period starting April 2014 to March 2016 (the most recent period for which data are available) was obtained. The workload in Gynaecology and Obstetrics undertaken at Caithness General before September 2015 and for six months after it, were obtained. The inpatient activity in Obstetrics was expected to have reduced due to the suspension of elective caesarean sections and primigravidae births at the hospital after September 2015.

Activity recorded by the datasets was less complete for the most recent quarterly periods and this over-estimated any reduction in activity measured before and after September 2015. National information provided by ISD was used to estimate the degree of completeness of the activity by quarter, by speciality and by dataset and applied to Caithness data, based on estimates at NHS Highland Health Board level.

The inpatient activity in Obstetrics and Gynaecology is shown in Figure 16. The number of consultant episodes in Obstetrics in the six months prior to September 2015 was 148 which reduced to 58 (62% reduction) in the six months after September 2015. If it is assumed that the degree of completeness in the SMR02 data set is similar at CGH to that for NHS Highland as a whole, then the actual reduction may have been slightly less at 58%. The decrease in inpatient/day case activity in Gynaecology was not as marked, decreasing from 117 patients to 71 patients in the six month period after September 2015 (39%). When correction for under-recording was applied, the reduction was lower at 34%. In terms of weekly workload, inpatient Obstetric activity in the quarter preceding September 2015, was just over six cases per week reducing to a little over three cases per week after that date. The corresponding activity for inpatient/day case activity in Gynaecology was 4.6 cases per week reducing to 4.0 cases per week.

Figure 17: Inpatient activity in Obstetrics and Gynaecology at Caithness General before and after the September 2015.



Data sources: SMR02 for Obstetrics; SMR01 for Gynaecology

Completeness of data: <u>SMR02</u>: April 2014 to Sept 2015 100%; Oct 2015 to Dec 2015, 95% : Jan 2016 to Mar 2016, 89% <u>SMR01</u>: April 2014 to Mar 2015 100%; April 2015 to Dec 2015, 94%-96%; Jan 2016 to Mar 2016, 71%

The outpatient activity in these specialities did not change significantly when comparing the six month periods before and after September 2015. The number of new outpatient attendances decreased from 179 to 153 cases (15%) and the number of return attendances increased from 240 to 264 cases (10% increase), see figure 17. In terms of weekly workload, the new patient antenatal activity was 3.3 cases before and 3.8 cases per week after September 2015. In contrast, new outpatient activity in Gynaecology showed a small decrease from 10.3 cases per week to 6.5 cases per week. There was a small decrease in antenatal obstetrics return activity from 9.1 to 8.5 cases per week.
Figure 18: Outpatient activity in Obstetrics and Gynaecology at Caithness General before and after September 2015



Source: SMR00 activity: Completeness of data: April 2014 to March 2015 100%; April 2015 to March 2016, 99%

1.9 Conclusion

This section of the report has examined available routine data sets to inform reflection of services in CGH. The evidence provided indicates that CGH draws on a very small hinterland, which is likely to reduce further over time. Several datasets call into question the safety of the EGAMS 2a service model provided at CGH and suggest that the population would be better served by a CMU. This tentative conclusion is developed further in future chapters.

2 Review of the literature

The results of the review of the literature are presented below, supplemented by local data that relates to issues identified in the literature review.

2.1 Risks associated with elective caesarean section

The first literature review undertaken answered the question, "What are the risks to the mother or to the foetus/newborn due to elective caesarean section when there are no paediatricians, no PICU, and no adult intensive care unit?"

In addition to a literature search undertaken locally, the search question was also sent to the CLEAR service hosted by the Knowledge Network, which in turn referred the request to the Health Management Library of NHS National Services, Scotland. The following combines the results of the local and NSS library searches.

2.1.1 Resources searched

Databases	Other resources
Health Management Library	NICE
Medline	ISD
Embase	Top of Form
	SCASMM reports (Scottish Confidential Review of
	Severe Maternal Morbidity: reducing avoidable harm)
Cochrane Library	The UK Obstetric Surveillance System
MIDIRS Maternity and Infant Care	MBRRACE reports
	EuroPeristat
	Secondary sources (e.g. to those NICE cites)

The following databases were searched.

2.1.2 Definitions used

The following definitions were used:

- An elective caesarean is one that takes place before labour begins as opposed to an emergency one that takes place during labour because of complications.
- An elective caesarean is a planned procedure when a medical need for the operation becomes apparent during pregnancy or if it is requested by the mother in advance.

In addition to a maternal request, some of the reasons for undertaking an elective caesarean are presented in table 4.

Table 4: Medical reasons for planned caesarean sections

1. Previous caesarean and	5. Serious maternal	9. Previous vaginal tear
felt safer to do so again	medical condition	
2. Multiple pregnancy	6. Transverse presentation	10. Infectious disease
3. Large baby for pelvis	7. Placenta praevia	11. Severe pre-eclampsia
4. Breech presentation	8. Placenta dysfunction	

Only some of the reasons in the above list are relevant to the situation in Caithness as they are similar to the transfer (exit) criteria used by CGH at the time of the death of the baby in September 2015.

2.1.3 NICE guidance

Recommendations laid out in the NICE guidance (CG132, Aug 2012) which are relevant to the situation of a lack of paediatric support and intensive care for mother are listed below:

- (1) The risk of respiratory morbidity is increased in babies born by CS before labour, but this risk decreases significantly after 39 weeks. Therefore, planned CS should **not** be carried out before 39 weeks.
- (2) Singleton breech at term, but where cephalic version is contraindicated or unsuccessful, **should be** offered CS as it reduces perinatal and neonatal morbidity.
- (3) CS **should not** be offered routinely in twin pregnancies where the presentation of the first twin is cephalic. Although there is no consistent evidence, it is current practice to offer CS when the first twin is not cephalic.
- (4) CS should not be routinely offered for pre-term births nor for small for gestation age babies.
- (5) CS **should be** offered where the placenta partly or completely covers the internal cervical os (i.e. minor or major placenta praevia).
- (6) If CS is performed for a delivery associated with morbidly adherent placenta, then an Obstetrician, Anaesthetist and an experienced Paediatrician **should be** present. A senior Haematologist should be available for advice, a critical care bed available. All hospitals should have a locally agreed protocol for managing these patients.
- (7) There are detailed specifications regarding mother to child transmission of maternal infections in which planned CS does not reduce the risk of transmission relative to a vaginal delivery-these mainly apply to women receiving antiviral medication for HIV.
- (8) A BMI of ≥50 should not alone indicate a need for a planned CS
- (9) An appropriately trained practitioner skilled in the resuscitation of the newborn **should be** present at CS performed under general anaesthesia, or where there is evidence of foetal compromise.
- (10) Although rare, professionals should be aware that the need for intensive care for the mother is more frequent following CS delivery.

The following tables summarise the relative effects on mothers' and babies health according to the evidence presented in the NICE guidance (CG132). These effects apply only where there is planned CS in women with uncomplicated pregnancy and no previous CS.

Table 5: Effects on maternal health that appear to be associated with a less desirable outcome in a planned CS relative to vaginal delivery

Parameter	Planned CS birth	Planned vaginal birth	Absolute effect	Quality of evidence ¹
Length of stay in hospital	3.2 days &	2.6 days &	0.6 days & 1.4	Low - Very
	3.96 days	2.56 days	days longer	low
Hysterectomy due to	0.03%	0.01%	14 (95% CI 3-33)	Very low
postpartum			more per	
haemorrhage			100,000	
Cardiac arrest	0.19%	0.03%	15 (95% CI 11.5-	Very low
			19.5) more per	-
			100 000	

Source: NICE Guidance (CG132, August 2012) ¹A four point quality rating adopted by NICE; N.B: CI = Confidence Interval;

Table 6: Effects on maternal health that appear to be associated with a more desirable outcome in planned CS relative to vaginal delivery

Parameter	Planned CS birth	Planned vaginal birth	Absolute effect	Quality of evidence ¹
Perineal and abdominal pain during birth	Median score 1.0	Median score 7.3	6.3 lower	Very low
Perineal and abdominal pain 3 days postpartum	Median score 4.5	Median score 5.2	0.7 lower	Very low
Injury to vagina	0.0%	0.56%	6 (95% CI 2-6) fewer per 100,000	Very low
Early postpartum haemorrhage	1.1%	6%	49 (95% CI 4-56) fewer per 100,000	Low
Obstetric shock	0.006%	0.018%	12 (95% CI 0.1- 17) fewer per 100,00	Very low

Source: NICE Guidance (CG132, August 2012) ¹A four point quality rating adopted by NICE; N.B: CI = Confidence Interval;

Table 7: Effects on babies' health that appear to be associated with a less desirable outcome in CS relative to vaginal delivery

Parameter	Planned CS birth	Planned vaginal birth	Absolute effect	Quality of evidence ¹
NICU admission	13.9%	6.3%	76 (95% CI 31- 134) more per 1000	Low

Source: NICE Guidance (CG132, August 2012) ¹A four point quality rating adopted by NICE N.B: CI = Confidence Interval;

The guidance also refers to care to the mother and baby after CS and two of these are relevant for a unit without intensive care facility and Paediatric support:

A **Care of Mother**: Healthcare professionals should be aware that although rare, the need for intensive care following childbirth occurs more frequently after CS (around 9 per 1000).

B **Care of baby born by CS**: An appropriately trained practitioner skilled in the resuscitation of the newborn should be present at CS performed under general anaesthesia, or where there is evidence of foetal compromise.

It should be noted that in support of each of these statements, the update of the NICE guidance in 2011 had not provided any additional evidence to that used in the original guidance of 2004. The sources of evidence for these two recommendations of care have been looked at and any additional evidence in relation to them arising from the local literature search has been included, as described in the following content.

2.1.4 Risk to mother: need for intensive care

The statement in NICE of a requirement for ICU care of around 9 per 1000 (0.1-0.9%; p166) was based on secondary references cited in a study published in 1996 (Wheatley *et al.*, 1996 (521 ref in NICE). The evidence of an increase in the need for intensive care due to planned CS came from a case control study in the USA (Panchal S *et al.*, 2000). The overall rate of admission to an intensive care unit (ICU) was 0.13% and the odds of admission to ICU was significantly higher for women who had CS compared with those who had vaginal birth, after adjustment for socio-demographic factors (age and ethnicity) and type of hospital (OR 9.0, 95% CI 7.24 - 11.16). The interpretation of this result is confounded by not being able to dissociate the effect of CS from the reasons for CS. The results of the National Sentinel CS Review suggests that 10% of cases having CS require special care post-operatively within a high dependency unit, and that 3.5% of these women were transferred to an intensive care unit (Thomas J *et al.*, RCOG). However, this is for all CS, and did not distinguished elective from emergency CS, or take into account whether the pregnancy was classed as being high risk.

More up to date evidence for any additional need for HDU/ICU derives from the measurement of the risk of severe acute maternal morbidity (SAMM) in relation to mode of delivery (van Dillen J *et al.*, 2010). The results were based on a prospective cohort study (n= 355,841) in the Netherlands. SAMM was defined as one of five categories: ICU admission, uterine rupture, eclampsia, major obstetric haemorrhage and miscellaneous. The authors estimated the incidence of SAMM which could be related to a planned CS per se as 0.64% compared to 0.39% for a planned vaginal delivery (OR = 1.7; 95% CI 1.4-2.0). The risk of SAMM in those who had a previous CS was three times higher than the total obstetric population risk with the proportion of all those with SAMM who had a previous CS at nearly one fifth (18.8%) compared to the general obstetric population at 7.2%.

Other evidence of increased need for ICU due to planned CS delivery was obtained from a Cochrane systematic review, which compared planned CS versus vaginal delivery in pre-term birth of singletons (Alfirevic Z *et al.*, 2013). There was no data relating to admissions to ICU but there were seven cases of major maternal postpartum complications in the group allocated to 'planned CS'. However, there were small numbers in the included studies (n = 116) and NICE guidance does not recommend planned CS in preterm infants.

A case control study involving 178 low risk obstetric pregnancies in Austria compared the maternal outcomes of planned CS with spontaneous vaginal births (Bodner K *et al.*, 2011). All included deliveries were in low risk women with a single pregnancy in cephalic presentation, normal sized foetus, a reactive admission cardiotocography and a gestational age >37 weeks. The study excluded repeat caesareans. Statistically significant higher incidence of maternal morbidity was measured including puerperal febrile morbidity and wound infections. The gestational age varied between 37 weeks and 42 weeks, the average being 40 weeks in each group.

A Cochrane systematic review included the maternal outcomes of planned caesarean sections in women with singleton breech presentation at term (Hofmeyr GJ *et al.*, 2015). From three studies (n =2,396) it showed significantly higher short term maternal morbidity in the planned CS group compared to spontaneous vaginal delivery (OR=1.29, 95% CI 1.03 to 1.61). The review did not specify which of the list of maternal outcomes was included other than abdominal pain.

A Swedish case control study (Karlstrom A *et al.*, 2013) measured maternal and neonatal outcomes associated with planned CS in women based on maternal request only (n= 5,877) compared to deliveries from spontaneous onset of labour (n = 13,774). Only elective CS with singleton cephalic babies were included. The risk of bleeding complications was higher (OR=2.5, 95% CI 2.1-3.0) as was breastfeeding complications (OR=6.8, 95% CI 3.2-14.5) and equated to 2.5% and 1.2% of the whole elective CS group respectively. Risk factors other than the mode of delivery were not accounted for and this included higher BMI, older age, and multi-parity and shorter length of pregnancy all of which were statistically different in the CS group compared to the spontaneous vaginal delivery group. The number of women with previous CS in the different groups was not reported.

A more recent study (Hutcheon JA *et al.*, 2015), based in Canada reported the results of implementing a hospital policy to limit low risk planned CS deliveries before 39 weeks of gestation using an interrupted time series analysis. The design was a retrospective cohort with the starting rate of CS before 39 weeks of 60%, dropping to 40% during the study period. There was no significant reduction in either neonatal or maternal morbidity, but the probability of an out of hours delivery was increased from 16% to 21%.

2.1.5 Summary

The additional evidence supports there being an excess risk of maternal morbidity with elective CS ranging from infection, and difficulties with breastfeeding to the need for ICU (major obstetric haemorrhage). This may represent for the more severe morbidity, an almost two fold increased risk but in absolute terms, this may only reflect an increase from 3.9 per 1000 to 6.4 per 1000 (NNH = 400). There was evidence of increased maternal morbidity for planned CS in those with previous CS. There is evidence from a Cochrane systematic review that planned CS for pre-term births is associated with higher risk of maternal need for ICU.

Whilst the NICE guidance recommends offering planned CS when cephalic version is not possible or contraindicated in singleton breech deliveries at term due to reduced neonatal and perinatal morbidity, a more recent Cochrane review reported increased maternal morbidity rate in 'planned CS', in term breech singleton delivery. However, these risks to the mother may be outweighed by the decrease in the risk to the neonate (see next section).

There is evidence from several studies to support the NICE recommendation of undertaking planned CS at \geq 39 weeks as opposed to an earlier gestational age. Based on this review, and based on the NICE guidance, the elective CS population that would be at the least risk of requiring admission for intensive care would be:

CS deliveries with least risk of maternal morbidity:

- Deliveries at ≥39 weeks
- No previous CS
- No general anaesthesia
- No singleton/twin breech

Conclusion: A search of the literature provides support for the conclusion in NICE guidance that elective CS should not be carried before 39 weeks.

2.1.6 Care of the neonate delivered by elective CS and the need for neonatal paediatric support

There is a clear recommendation by NICE that paediatric support, in terms of an appropriately skilled practitioner in resuscitation, should be present when CS is performed under general anaesthesia or when foetal distress is evident. No new sources were added to this statement in CG132, Aug 2012. The local review has added some evidence to the timing of elective CS in terms of reducing respiratory neonatal morbidity and to the stratification of high or low risk pregnancies.

A Cochrane systematic review, which compared planned CS versus vaginal delivery in pre-term birth of singletons (Alfirevic Z *et al.*, 2013) failed to find any worse neonatal outcomes compared to planned vaginal birth. The outcomes examined included perinatal deaths, birth asphyxia or Apgar score. There was no data reporting on neonatal intensive care admissions. However the number of cases was low (n =116) and the authors recommend larger and further RCTs.

A descriptive study analysing admissions to a Special Care Neonatal (SCN) unit at a tertiary hospital in Australia reported significantly higher rates of admission of term neonates (≥37 weeks) from elective CS than from spontaneous vaginal delivery (Alkiaat A *et al.*, 2013). During the study period, there were 1,671 admissions to the SCN representing 14.4% of all term deliveries. The most common reasons for admission were respiratory complications (25%), post-resuscitation (24%) and hypoglycaemia (9%). Of the neonates admitted to SCN after elective CS, 37% were due to respiratory complications, which was significantly higher than the 23% admitted after all other delivery modes. This disparity was higher for those neonates delivered before 39 weeks of gestation (38% versus 24%). However, there was no stratification for low and high risk pregnancies and there were higher rate of risk factors in the maternal population associated with neonatal care unit admission. These included nulliparity, hypertension and diabetes. Thus if the maternal population had a greater prevalence of risk factors compared to other modes of delivery, some of this excess proportion of ICU admission due to respiratory problems may reflect this factor rather than that of the actual mode of elective CS delivery itself.

In terms of rural and disadvantaged communities, a retrospective descriptive study based on an obstetric population in Appalachia, measured a 4.4 times greater risk of admission to neonatal intensive care, 2.5 times more likely to develop jaundice and 7.7 times likely to be underweight in those delivered electively at early term (37-38 weeks) compared to those delivered electively at \geq 39 weeks (Bailey BA *et al.*, 2014). Those living furthest away from the hospital were most likely to deliver electively before 39 weeks. However the elective deliveries (n = 638) included both the elective modalities of CS and induction and there was no stratification in terms of high and low risk births, making it difficult to interpret these results in terms of the risk of elective CS per se.

A case control study involving 178 low risk obstetric pregnancies in Austria compared the maternal and neonatal outcomes of planned CS with spontaneous vaginal births (Bodner K *et al.*, 2011). All included deliveries were in low risk women with a single pregnancy in cephalic presentation, normal sized foetus, a reactive admission cardiotocography and a gestational age >37 weeks. The study excluded repeat CS.

The results in terms of increased maternal morbidity in the elective CS cases have been noted in the section on the care of the mother above. The prevalence of neonatal outcomes, however, in terms of Apgar score, cord pH and neonatal infections were low in both groups with no statistically significant differences observed, perhaps due to sample size. The gestational age varied between 37 weeks and 42 weeks, the average being 40 weeks in each group.

A randomised control trial (Glavind J *et al.*, 2012) compared the neonatal outcomes of elective CS in two groups of low risk women (singletons, reliable gestational age, uncomplicated pregnancies no diabetics and no high risk of having an elective CS before 39+5 weeks). The women (n = 1,274) from seven Danish hospitals were randomised to those having an elective CS at 38+3 (+/-two days) or at 39+3 (+/-two days) of gestation. Using a neonatal outcome of admission to a neonatal intensive care unit within 48 hours of delivery, there was no statistical significant difference between the two groups viz. 13.9% admitted in the 38+3 weeks and 11.9% in the 39+3 weeks group. A statistical significant difference may have been prevented by too small a sample size.

A Cochrane systematic review, which was included in the previous section on maternal care, also included the neonatal outcomes of planned caesarean sections in women with singleton breech presentation at term (Hofmeyr GJ *et al.*, 2015. The authors used the results from three studies (n =2,396) but the results in terms of perinatal or neonatal severe morbidity or death were heterogeneous. For settings in which the national perinatal mortality rate was low, elective CS significantly reduced adverse neonatal outcomes (one study, n = 1,025; RR=0.07, 95% CI 0.02 - 0.29). With a random-effects analysis, the perinatal or neonatal death rate was reduced with planned CS (RR = 0.29, 95% CI 0.10 - 0.86) in the three studies (n = 2,078) compared to planned vaginal birth.

A Swedish case control study (Karlstrom A *et al.*, 2013) measured neonatal as well as maternal outcomes (see previous section on maternal care) associated with planned CS in women based on maternal request (n= 5,877) compared to deliveries from spontaneous onset of labour (n = 13,774). The latter control group was also stratified into those who went on to have vaginal delivery and those who had emergency CS. Infant outcomes showed a higher incidence of respiratory distress (2.7%) in the elective CS group (OR = 2.7, 95% CI 1.8 to 3.9) than infants born by spontaneous vaginal delivery (1%). It was also higher in the emergency CS group (2.5%). Risk factors other than the mode of delivery were not matched for and this included higher BMI, older age, and multi-parity and shorter length of pregnancy all of which were statistically different in the CS group compared to the spontaneous vaginal delivery group. Not reported was the number of women with previous CS in the groups.

A single centre study in Egypt prospectively followed 200 women who underwent elective CS at 38 or 39 weeks gestation and recorded the incidence of respiratory morbidity in the neonates (Mostafa HS *et al.*, 2013). These women were obstetrically low risk, with no medical or obstetrical indications for delivery. They were all single pregnancies and women with medical conditions such as diabetes, hypertension, intra-uterine growth retardation, pre-eclampsia, antepartum haemorrhage or ruptured membranes as well as infants with meconium aspiration syndrome, sepsis, or pneumonia were excluded from the study. The authors reported a 2.7 higher risk of incidence (OR = 2.7, 95% CI 1.2-5.8) in the early gestation group; 25% versus 11% respectively.

Another retrospective study compared neonatal outcomes of elective CS delivery at 38 weeks (n = 390) with those at 37 weeks (n = 294), (Nakashima J *et al.*, 2014). Deliveries of high obstetric risk were excluded (multiple pregnancies, diabetes, hypertension, uterine growth retardation, PROM,

and others). Adverse respiratory complications, neonatal intensive unit admission, incidence of hypoglycaemia and low birth weight were significantly higher in the shorter term elective CS group.

A study in Israel reviewed elective CS deliveries (n = 12,276) of early term (37-38 gestational weeks) and late term (\geq 39 weeks) from one medical centre. Indication for elective CS were maternal request, recurrent CS, breech, macrosomia and active genital herpes. Multiple births, diabetes and emergent maternal conditions were excluded. Morbidity and admissions to neonatal intensive care unit was higher in the early term group (26/596 versus 11/454), (Nir V *et al.*, 2012).

A prospective study (Ozlu F *et al.*, 2012) based in a tertiary hospital in Turkey evaluated singleton newborns (n =545) delivered at ≥35 weeks from low risk pregnancies by elective CS for resuscitation steps. Overall, 27.5% needed supplemental oxygen and 4.2% of neonates needed bag and mask ventilation; none needed CPR or endotracheal tube insertion or adrenaline administration. The rates of supplemental oxygen and mask and bag ventilation were higher in the elective CS group, which had general anaesthesia. Gestational age was not associated with differences in resuscitation need. The authors concluded that there was no need for .paediatric attendance at elective CS deliveries of low risk pregnancies if there is attendance of a trained practitioner to perform bag and mask ventilation when needed.

A similar study (Tooke LJ *et al.,* 2011) based in South Africa prospectively evaluated the need for a paediatrician from 115 elective CS that were classified as low risk which excluded general anaesthesia, multiple pregnancy, prematurity, growth restriction, abnormal lie, known congenital abnormality. One out of the 115 required brief resuscitation (0.9%). The authors concluded that there was no need for paediatrician attendance at low risk elective CS. No power calculation was reported for this outcome and it can be argued that the sample size was too small to reach a clear conclusion in relation to neonatal paediatric care. This conclusion was reached in a medium income country, where a much higher perinatal mortality rate is accepted compared to the UK. The conclusion cannot be generalised to the CGH situation.

2.1.7 Summary

For term deliveries (≥37 weeks), elective CS compared to spontaneous vaginal delivery was associated with a higher incidence of neonatal morbidity, and/or increased admission to special care or neonatal intensive care units in two studies but in two other studies, there was no statistically significant difference found. The differing results may be due to study design.

The results from several studies (n =5) support the NICE recommendations of minimising complications, particularly respiratory problems in the neonate by undertaking the elective CS at full term (\geq 39 weeks) rather than early term (37-38 weeks). However, all these studies were descriptive (retrospective or prospective). The findings from a single RCT did not support the higher rates of morbidity in early term elective CS.

There was high level evidence that elective caesarean section in single breech delivery reduced neonatal morbidity. In the same meta-analysis, increased maternal morbidity was also measured but the severity of the morbidity was not indicated.

Two medium income country studies addressed the need for paediatric support with elective caesarean sections. One was based in Turkey and the other in South Africa. Both concluded that the key need was appropriately trained staff to undertake bag and mask ventilation of the neonate. The studies concluded that this could be someone other than a paediatrician. The design of the studies and the low sample sizes in both studies preclude any clear conclusions in regard of relative need for neonatal care. South Africa and Turkey are contexts where infant mortality is

much higher than is acceptable in the UK³, so the conclusions in these papers cannot be generalised to a UK situation including that of the CGH situation.

Conclusion: There is a clear recommendation by NICE that paediatric support, in terms of appropriately skilled practitioner in resuscitation, should be present when CS is performed under general anaesthesia or when foetal distress is evident. The NICE guidance in the context of CGH, suggests that these types of CS should not be undertaken in CGH, as there is inadequate neonatal paediatric expertise available.

2.1.8 Overall conclusion regarding risk and elective CS

In relation to elective caesarean section, there appears to be an overall risk of 0.6% for 'severe maternal morbidity' representing a 'number needed to harm' of 400, or one in 400 cases. In terms of the neonate, it has proved difficult to arrive at a rate but in terms of the need for special neonatal care, this might be as high as 14% based on a descriptive study design. The latter was a rate measured in all term (≥37 weeks) babies not stratified for high or low risk pregnancies. This rate is likely to be significantly lower if only low risk pregnancies were involved, and if only full term deliveries (≥39 weeks) are included. There was high level evidence of increased maternal morbidity of single breech deliveries by elective CS although the severity of the morbidity was not indicated. Conversely, there was evidence of reduced neonatal morbidity for single breech deliver CS.

Conclusion: Given the increased risk of respiratory problems in neonates after elective CS and the fact that the need for special neonatal care may be as high as 14%, elective CS should not be undertaken at CGH.

2.2 Risks associated with births to primigravidae

The second literature review question addressed was, "What are the risks to the mother or newborn in first pregnancy births across different birth settings?" Specifically:

- 1. What are the absolute rates of complications to the mother or newborn in first pregnancy births?
- 2. Are the rates of interventions (including forceps or vacuum extraction⁾, transfers and adverse outcomes for primigravidae women different in different birth settings?
- 3. What risk factors in pregnant women are associated with higher rates of complications during delivery and after birth for mother or neonate in first pregnancy births?

The sources that were searched included:

- (1) Evidence based guidelines on intrapartum delivery e.g. NICE (CG190)
- (2) Professional Guidance e.g. RCOG (R. Coll Obstet and Gynae); RCM (R. Coll Midwives) including minimum standards set
- (3) Results of inquiries into maternity services, e.g. The Report of the Morecambe Bay Investigation⁴

³ Demirel, G., Tezel, B., Ozbas, S., Oguz, S.S., Erdeve, O., Uras, N. and Dilmen, U., 2013. Rapid decrease of neonatal mortality in Turkey. *Maternal and Child Health Journal*, 17(7), 1215-1221.

- (4) Evidence reviews for safe births e.g. National Perinatal Epidemiological Unit
- (5) Publications of surveillance of maternal deaths, still births and neonatal deaths (MBRRACE)
- (6) Search of King's Fund and other independent bodies
- (7) Specific searches of OVID databases, TRIP and the Cochrane Library

For this review to be informative, the evidence sought relates to only births to primigravidae women that were considered to be at low risk, i.e. excluding those with known risk factors for higher risk births, since these would have been preferentially booked at Raigmore hospital or a hospital out with the Health Board area depending on the particular risk. There was no universally agreed list of what constituted low risk although many publications cite the NICE guidance of 2007 (CG55) and the more recent CG190 (Dec. 2014). These factors are listed in tables 8 & 9.

Table 8: Medical conditions indicating increased risk suggesting planned birth at an obstetric unit

Disease Area	Medical condition
Cardiovascular	Confirmed cardiac disease
Carulovasculai	Hypertensive disorders
Respiratory	Asthma requiring an increase in treatment or hospital treatment
Respiratory	Cystic fibrosis
	Haemoglobinopathies: sickle-cell disease, beta-thalassaemia major
	History of thromboembolic disorders
	Immune thrombocytopenia purpura or other platelet disorder or platelet
Haematological	count below 100,000
riacinatological	Von Willebrand's disease
	Bleeding disorder in the woman or unborn baby
	Atypical antibodies which carry a risk of haemolytic disease of the
	newborn
	Risk factors associated with group B streptococcus whereby antibiotics in
	labour would be recommended
	Hepatitis B/C with abnormal liver function tests
Infontivo	Carrier of/infected with HIV
mective	Toxoplasmosis – women receiving treatment
	Current active infection of chicken pox/rubella/genital herpes in the
	woman or baby
	Tuberculosis under treatment
Immuno	Systemic lupus erythematosus
IIIIIIulie	Scleroderma
Endocrino	Hyperthyroidism
LINUOCIIIIE	Diabetes
Popal	Abnormal renal function
Renal	Renal disease requiring supervision by a renal specialist
Neurological	Epilepsy
	Myasthenia gravis
	Previous Cerebrovascular accident
Gastrointestinal	Liver disease associated with current abnormal liver function tests
Psychiatric	Psychiatric disorder requiring current inpatient care

⁴The Report of the Morecambe Bay Investigation

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/408480/47487_MBI_Accessible_v0.1.pdf

Source: NICE Guideline on intrapartum care (CG 190)

Further factors are provided in the table below.

Factor	Additional information
	Unexplained stillbirth/neonatal death or previous death related to
	intrapartum difficulty
	Previous baby with neonatal encephalopathy
	Pre-eclampsia requiring preterm birth
	Placental abruption with adverse outcome
Previous	Eclampsia
complications	Uterine rupture
	Primary postpartum haemorrhage requiring additional treatment or
	blood transfusion
	Retained placenta requiring manual removal in theatre
	Caesarean section
	Shoulder dystocia
	Multiple birth
	Placenta praevia
	Pre-eclampsia or pregnancy-induced hypertension
	Preterm labour or preterm pre-labour rupture of membranes
	Placental abruption
	Anaemia – haemoglobin less than 8.5 g/dl at onset of labour
	Confirmed intrauterine death
Current program	Induction of labour
Eatal indications	Substance misuse
I etal mulcations	Alcohol dependency requiring assessment or treatment
	Onset of gestational diabetes
	Malpresentation – breech or transverse lie
	Body mass index at booking of greater than 35 kg/m2
	Recurrent antepartum haemorrhage
	Small for gestational age in this pregnancy (less than fifth centile or
	reduced growth velocity on ultrasound)
	Abnormal foetal heart rate (FHR)/Doppler studies
	Ultrasound diagnosis of oligo-/polyhydramnios
Previous	Myomectomy
gynaecological	Hysterotomy
history	

Table 9:	Other factors	indicating	increased	risk suaaes	ting planned	birth at ar	obstetric unit
	•						

Source: NICE Guideline on intrapartum care (CG 190)

2.2.1 What are the absolute rates of complications to the mother or newborn in first pregnancy births?

The first literature review question addressed in the section was, "Are the rates of interventions (including forceps or vacuum extraction⁾, transfers and adverse outcomes for primigravidae births different in different birth settings?"

The Royal College of Obstetricians and Gynaecologists (RCOG), (Good Practice Guide no. 15, Dec. 2013) provides a working estimate for service planning pertaining to the whole population of pregnant women as follows:



Figure 19: Estimated proportions of pregnancies by risk category

* Mainly those with previous uneventful births-<5% need transfer ** Mainly primagravida, managed antenatally as low risk of which 25% will require specialist care (maternal hypertension/foetal growth restriction) *** due to complications in previous births or in current pregnancy

Data source: Good Practice No. 15, RCOG 2013

According to the above, approximately one quarter of primigravidae women will require specialist care before labour compared to <5% of low risk multiparous women.

2.2.2 Are the rates of intervention, transfers and adverse outcomes for primigravidae births different in different birth settings?

The second literature review question in this section was, "Are the rates of interventions (including forceps or vacuum extraction⁾, transfers and adverse outcomes for primigravidae different in different birth settings?"

The main source of the incidence of complications during pregnancy is derived from the birthplace cohort study undertaken by the National Perinatal Epidemiology Unit (NPEU) of Oxford University (Brocklehurst P et al., 2011 BMJ 2011; 343:d7400). This study measured the pregnancy and neonatal outcomes of 64,500 women giving birth in England during the two year period between 2008 and 2010. Women were eligible if: they were expecting singletons, had a planned place of birth, and were deemed at low risk before the onset of labour, based on NICE 2007 and 2014 criteria. Primary outcomes included perinatal mortality and specific neonatal morbidities (still birth after the start of care in labour, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus and fractured clavicle). The overall incidence rate of a neonatal primary outcome was 4.3 (95% CI 3.3 - 5.5) per 1000 births (equivalent to approximately 1 in 250 births) and there was no difference in rates between planned place of birth settings. When stratified by parity the rate was 5.3 (95% CI 4.0 - 7.0) per 1000 (approximately 1.33 in 250 births) in nulliparous women but unlike multiparous women, the rate in the home-birth setting was higher at 9.3 (95% CI 6.5 - 13.1). This was statistically higher than the rate in Obstetric-led units when the analysis was restricted to only those births which according to attending midwives, were not associated with any complicating condition at the start of labour. The rates of neonatal primary outcome in nulliparous women in midwife led units whether free standing

(FMU) or alongside obstetric units (AMU), were similar to that in the obstetric-led unit setting both when based on the full cohort of low-risk women and when based on the restricted cohort of low risk at the start of labour.

The transfer rate to an obstetric unit during labour and immediately before delivery was higher in nulliparous women than in multiparous women and was 35% versus 6% for planned home births, 30% versus 5% for planned FMUs and 34% versus 9% for planned AMU births. The overall transfer rates, which include those occurring immediately after birth in nulliparous women, were: 36% and 40% in FMU and AMU respectively.

Similarly, the labour intervention rate (defined as augmentation, epidural/spinal analgesia, general anaesthesia, vacuum extraction or forceps delivery, caesarean section, episiotomy) was higher for planned obstetric units (42%) than for AMU (24%) or FMU (17%). The study did not stratify these intervention rates by parity but the rates were still significantly higher in obstetric-led units when the analysis was restricted to the low-risk cohort as defined at the start of labour.

Maternal outcomes in comparison to obstetric-led planned deliveries of low risk women as measured by third or fourth degree perineal trauma, maternal blood transfusion or maternal admission to higher level of care were generally lower in FMU setting. This was statistically so for all outcomes with the exception of third or fourth perineal trauma (OR =0.78, 95% CI 0.58 - 1.05).

The largest differences between the types of planned birthplaces was in parity, with 27% home births, 46% FMUs, 50% AMUs and 58% of obstetric units being nulliparous.

Analysis of the Birthplace cohort study has been published in a series of reports by the National Perinatal Epidemiology Unit and as ten separate papers in peer reviewed journals (mainly BMJ and BJOG). The National Perinatal Epidemiology Unit Report 2 (Hollowell J *et al.*, 2015) included additional analysis with stratification by parity, which provides absolute risks of complications before labour, interventions and maternal and perinatal outcomes. However, it was restricted to non-obstetric led units including home births and used AMU as reference. Consistent with the original publication of the Birthplace Cohort study, primigravidae planned births at FMUs were associated with a rate of perinatal outcome of 0.5%, which did not differ from that of AMU planned births. The rates of maternal outcomes for FMU planned births were: 79% for straight forward vaginal birth, 11% instrumental delivery, 7% intrapartum CS, 4% 3rd or 4th degree perineal trauma, 0.8% blood transfusion and 0.2% maternal admission for higher care. The rates of vaginal delivery and maternal admissions for higher level care were all statistically "better" in planned FMU births than in AMU planned births.

The original analysis reported significantly higher maternal intrapartum transfer rates from midwifery units, in the order of 4-6 times, in nulliparous pregnancies than in multiparous pregnancies. A further analysis of the transfer data (Rowe RE *et al.*, 2012) provided stratification of the rates by maternal characteristics and reason for transfer. In this analysis, the rate of maternal transfers (during labour or within 24 hours of birth), were 21% and 27% for planned births in FMU and AMU respectively. The majority were in the intrapartum period with absolute rates of postnatal transfer of 5% and 4% respectively. The most common reason for transfers was failure to progress in first stage followed by failure to progress in second stage. Transfer for neonatal reasons made up a small proportion of all transfers but was higher in FMU (3%) than in AMU (0.1%). These proportions equated to absolute rates of 0.6% and 0.03% respectively. Absolute transfer rates were higher in nulliparous women than in multiparous women in each type of unit, 35% in FMU and 40% in AMU compared to 9% and 13% respectively. The rates in nulliparous women increased with age (see section 2.24 for more detailed results by) so that nulliparous

women aged ≥35 years were associated with seven times the rates of transfer than multiparous women aged 25-29 years. For both multiparous and nulliparous women, the rate of transfer was 35-38% higher in pregnancies lasting 41 weeks and over compared to those lasting 40 weeks.

2.2.3 Summary

A. Before birth: Approximately one quarter of all births **in** nulliparous women are classed antenatally as 'low risk', but some will be re-designated as 'high risk' and require step-up care to specialist services before labour, due to developing concerns such as maternal hypertension or foetal growth restriction. This compares to an equivalent rate of re-designation of <5% in 'low risk' multiparous women.

Conclusion: Women classed as at 'high risk' should always be offered the opportunity to give birth at Raigmore Hospital.

B. During and after labour

(1) For the neonate: A large prospective cohort study of low risk women has provided an overall incidence rate for neonatal adverse outcomes of 4.3 per 1000 (1 in 250) births. The rate is higher in nulliparous women at 5.3 per 1000 (1.33 in 250) births. The rates associated with nulliparous women in both types of Midwife-led unit were not different to that in Obstetric-led units but in the case of planned home births, they were significantly higher.

Conclusion: Women classed as at 'low risk' can safely be offered the opportunity to give birth at a CMU based in CGH, particularly if they have previously had an uncomplicated birth.

(2) For the mother:

(i) Maternal intra-partum transfer rates before delivery are higher in nulliparous women compared to multiparous women in each of the two types of midwife-led unit, 30% and 34% versus 5% and 9% for FMU and AMU respectively.

(ii) Intervention rates were significantly lower in each of the two types of midwife-led unit than in obstetric units, 17% (FMU) and 24% (AMU) versus 42% but analysis was not stratified for parity.

(iii) Maternal adverse outcomes were statistically significantly lower for two out of the three measured in FMU compared to Obstetric-led units, again not stratified for parity.

Conclusion: Redesign of services at CGH to provide a CMU will result in more women travelling to Raigmore Hospital. However, this should provide these mothers and their babies with safer outcomes.

Conclusion: Women who have been assessed as 'low risk' and who give birth in a CMU in CGH would expect to have fewer unnecessary interventions than is the case in the current obstetric-led (EGAMS 2a) unit. A local CMU would improve outcomes for these women.

2.2.4 What risk factors in pregnant women are associated with higher rates of complications during delivery and after birth for mother or neonate in first pregnancy births?

The third literature review question in this section was, "What risk factors in pregnant women are associated with higher rates of complications during delivery and after birth for mother or neonate in first pregnancy births?"

Another analysis of the Birthplace cohort study looked at the association of maternal and neonatal outcomes by age stratified by parity (Yi L *et al.*, BMJ Open 2015). Generally, interventions and adverse maternal outcomes requiring obstetric care increased with maternal age and this association was statistically significant in nulliparous mothers. Although the association was steeper for nulliparous women with a planned place of birth in a non-obstetric led unit, the absolute risks were higher at all ages in those with a planned place of birth in an obstetric-led unit (54% versus 31%).

The risk of a perinatal adverse outcome (neonatal admission or perinatal death) was significantly raised in nulliparous women aged 40 years and over relative to those aged 25-29 years (RR = 2.29, 95% CI 1.28 - 4.09). The absolute risk of an adverse perinatal outcome in nulliparous women was 3.7% (95% CI, 2.9% - 4.6%) in a planned obstetric-led unit and 2.6% (95% CI, 2.2% - 3.1%) in a planned non-obstetric unit for women aged 16 years and over. These rates pertained to low risk women as defined earlier. A further analysis of a restricted cohort which excluded all births where the attending midwife had noted a complication just at the start of labour reduced this absolute risk in nulliparous women to 2.9% (2.3% - 3.7%) in a planned obstetric-led unit and 2.4% (95% CI, 2.0% - 2.9%) in a planned non-obstetric unit for women aged 16 years and over. The absolute risks of interventions and adverse maternal outcomes requiring obstetric care were also lower in this restricted cohort with 48% in planned obstetric unit and 30% in planned non-obstetric unit.

The effects of maternal obesity on neonatal and maternal outcomes by parity were reported in another published article based on the Birthplace Cohort study (Hollowell J *et al.*, 2014). Based on low risk healthy women with a planned birth in an obstetric unit, outcomes pertaining to maternal weights of under- weight (<18.5 kg/m²), normal (18.5-24.9 Kg/m²), overweight (25-29.9 Kg/m²), obese (30-35 Kg/m²) and very obese (>35 Kg/m²) were reported.

The composite maternal outcome (interventions and adverse maternal outcomes combined) and the perinatal outcome (neonatal unit admission, intrapartum stillbirth/early neonatal death) increased in line with maternal weight, with relative risks of 1.17 and 1.14 respectively between obese and normal weight. However, the absolute risks were higher at all weights in nulliparous women compared to multiparous women particularly for maternal outcomes where a risk of 53% in normal weight nulliparous women contrasted with a 21% in obese multiparous women.

Most births in obese women are planned in obstetric units (according to NICE guidance 2007 and 2014, body weight greater than 35 kg/m² is associated with higher risk and is an indication for planned obstetric-led unit birth). So the main analysis only included planned births in obstetric units. However, there were supplementary data pertaining to midwife-led units provided albeit on much lower numbers. No consistent BMI gradient was seen with either maternal or perinatal outcome. Only one statistically significant difference with normal weight was noted pertaining to perinatal outcome in very obese mothers although based on small numbers (three out of 63 events). Due to small numbers, there was no stratification by parity.

Further evidence has been reported from secondary analysis of the Birthplace Cohort study which specifically explored maternal and organisational factors associated with intervention, transfer and other outcomes in each birth setting in 'low risk' and 'higher risk' women (Hollowell, J *et al.*, 2015, Chapter 4). Within each type of birthing setting in low risk nulliparous women, the risk of instrumental delivery, intrapartum CS, normal births, straightforward birth were not different with socio-economic deprivation although for each of these interventions/outcomes, the risks were "better" in the more deprived group.

However, further analyses showed that there was a statistically significant affect of socio-economic deprivation on the reduction of risk of intervention between an obstetric-led unit delivery and a non-obstetric unit delivery. In nulliparous women this applied to all the outcomes other than normal births whilst in multiparous women, the association was only with normal births. These statistically significant differences between more and less disadvantaged areas in the reduction in the risk of intervention associated with planning a non-Obstetric Unit birth relative to a obstetric unit were small, particularly when compared with the effect of birth setting per se i.e. irrespective of deprivation.

This is similar to the effect previously reported of maternal age on interventions and adverse maternal outcomes, where the differences in rates between Obstetric Unit settings and non-Obstetric Unit settings far outweighed any difference due to age per se.

The absolute risks in primigravidae births in Obstetric Units and CMUs from the Birthplace cohort study are tabulated below (table 10).

	Event rate per 1000 births				
Outcome/intervention	Obstetric-led units	Free-standing Mid-wife led unit	Any non- Obstetric		
Perinatal mortality and neonatal morbidity ¹	5.3 (3.9 to 7.3) ^a	4.5 (2.8 to 7.1) ^a			
Perinatal composite outcome ²	37 (29 to 46) ^b		26 (22-31) ^b		
Maternal composite outcome ³	544 (519 to 239) ^b		313 (293 to 334)		
Spontaneous delivery	420 ^c	700 ^c			
Maternal admission to higher care (HDU/ITU)	8 (5-14) ^b	2 ^d	8 (4-15) ^ь 10 ^d (AMU only)		
Instrument delivery ⁴	225 (199 to 253) ^b	108 ^d	145 (130 to 160) [♭]		
Intrapartum Caesarean Section	157 (141 to 175) ^b	65 ^d	76 (68 to 84) ^b		
Augmentation with syntocinon	346 (319 to 374) ^b		169 (157 to 181) [♭]		
Maternal tranfer ⁵		346 ^e			

 Table 10: Absolute rates of interventions and outcomes in low risk primigravidae births in

 different birth settings

Sources: ^aBrocklehurst P *et al.,* 2011; ^bLi Y *et al.,* 2015; ^cKurinczuk JJ *et al.,* 2015, Report 1; ^dHollowell J *et al.,* 2015, Report 2; ^eRowe R *et al.,* 2012

Notes:

¹ Still birth after start of labour, early neonatal death, neonatal encephalopathy, merconium aspiration syndrome, brachial plexus injury, fractured humerus and fractured clavicle

² Admission to a neonatal unit <48h, stillbirth after labour onset, early neonatal death

³Augmentation, instrumental delivery, intrapartum CS, general anaesthesia, blood transfusion,, 3rd/4th degree tear, maternal admission for higher care

⁴ Ventous or forceps

⁵ Transfers during labour or within 24h of birth for reasons other than neonatal concerns

Maternal factors associated with maternal and neonatal risks are summarised in table 11.

Table 11: Factors increasing the risk of events in low risk primigravidae

Factor	Effect
Increasing age	Positive gradient with maternal outcomes and interventions; steeper in a planned non-obstetric place of birth than in an obstetric unit (RR= 1.22 per 5 year age increase compared to 1.13 respectively), but absolute risk at any age always lower in planned non-obstetric unit. For any planned unit, the neonatal composite outcome (admission to neonatal unit or stillbirth after onset of labour or early neonatal death) was higher by 1.07 times for each 5 year age increase (not statistically significant). In nulliparous women, the risk was almost 30% higher in women aged 40 years and over relative to those aged 25 to 29 years-this was not the case in multiparous women. Rates of maternal transfer for non-neonatal reasons were higher with age, not so in multiparous women with rates 2-4 times lower at any age
Socio- economic status (SES)	Non –statistically significant "better" maternal outcomes were associated with more socioeconomic deprivation. There was a statistically significant impact of SES on the relative risks between planned births in Obstetric units and those in non-obstetric units.
Gestation	Transfers rates for non-neonatal reasons were 35-38% higher in gestations ≥41 weeks compared to 40 weeks for both nulliparous and multiparous women
Obesity	Composite maternal outcome and perinatal outcome (admission to neonatal unit or stillbirth after onset of labour or early neonatal death) were 17 % and 14% higher in obese women relative to normal weight in Obstetric units. The rates particularly maternal outcomes were always higher in nulliparous women at any weight; 530 per 1000 in nulliparous normal weight compared to 210 per 1000 in obese multiparous women

2.2.5 Other sources of relevant evidence

The most recent clinical guidance from NICE 2014 (Intrapartum care for healthy women and babies, cg190,) is relevant to nulliparous women, and is in keeping with the findings from the National Birthplace Cohort study. Indeed, it has used the study predominantly in comparing risks by place of birth although also making use of a cohort study based in Norway (Blix *et al.*, 2012). The latter was a smaller retrospective cohort (compared to the larger and prospective birthplace cohort study) study of low risk women. It compared hospital births with home births and confirmed the higher rates of interventions with a hospital birth. The study was too small to compare neonatal outcomes.

The NICE guidance makes little reference to maternal age and body weight other than indicating that women aged \geq 35 years and/or body weight 30-35 kg/m² should have individual assessment when planning place of birth and that a body weight >35 kg/m² suggests a planned birth at an obstetric unit.

The particular references to nulliparous pregnancies relate to:

(1) Advise low-risk women that planning birth in a midwifery unit is particularly suitable because the rate of intervention is lower and the outcome for the baby is no different to an obstetric unit.

(2) Planning births at home or in a FMU is associated with a higher rate of spontaneous delivery than at an AMU and all three settings in turn have higher rates of spontaneous delivery than at an obstetric unit.

(3) Whilst there is no difference in neonatal outcome in AMU, FMU and Obstetric Units, there is a higher rate of serious neonatal morbidity (approximately four more per 1000 births) for births at home.

2.2.6 Risks associated with primigravidae births

Using the results from the National Birthplace Cohort study:

A. Compared to multiparous, nulliparous births are associated with:

(1) Approximately one quarter will require step-up care before labour compared to approx. 3% of low-risk multiparous women.

(2) Higher neonatal adverse outcomes (5.3 per 1000 vs. 4.3/1000), although the difference was not statistically significant.

(3) 4-5 times higher maternal intrapartum transfer rates from midwife-led units.

B. Nulliparous births in Obstetric led units are associated with:

(1) Non-statistically significant higher rate of neonatal adverse outcomes than those in FMU.

(2) Significantly higher maternal intervention rates than non-obstetric place.

(3) Significantly higher maternal adverse outcomes than non-obstetric place.

(4) Similar maternal admission to higher care than non-obstetric place (eight per 1,000) but rate in FMU is significantly lower than AMU (2 per 1000 versus 10 per 1000).

C. Maternal factors affecting births in nulliparous women:

(1) Higher risk of maternal adverse outcomes and maternal interventions with maternal age (22% per five year increase) in non-obstetric place of birth (nulliparous only)

(2) Higher risk of maternal transfer for non-neonatal reasons with increasing maternal age (nulliparous only).

(3) Relative risk of adverse maternal outcomes association with obstetric versus non-obstetric places of birth affected by socio-economic status.

(4) Obesity versus normal weight associated with higher risk of adverse maternal outcome (17%) and neonatal outcome (14%) but absolute risk at normal weight is 2.5 times higher than risk in obese multiparous women.

Conclusion: The report recommends that CGH provide intrapartum care for primigravidae mothers in a CMU setting once midwifery staff are confident with the model of care and their practice.

Conclusion: All mothers delivering at CGH must be fully and clearly informed of the risks and benefits of delivery at CGH or Raigmore hospital in coming to a decision as to where they would like to give birth.

3 Review Methods

The methodology described below relates internal work to address objectives 1 and 2

3.1 Internal review of a random sample of case notes (Objective 1)

Objective 1 was to assess compliance with EGAMS and Caithness maternity transfer (exit) criteria for antenatal booking, intrapartum, neonatal and postpartum care. To do this, a sample size was required which was sufficiently large to be representative of the 163 births occurring during the period Sept 2014 to Aug 2015 (incl.) in CGH. The minimum sample size required was based on an assumption of an "event" rate of around 6.3%. This was the average actual annual transfer rate from the Caithness unit measured from SMR02 data over a 4 year period (2010-2014). Using this rate assumed that there could be at least the same number of incidents that did not result in transfer. Advice from an external statistician (NMAHP Research unit of the University of Stirling) was to undertake the review of 20 case notes in the first instance, so as to determine a likely incident rate, which would then allow computing the actual sample size needed. In the event, the Technical Review team agreed to review 60 notes in total using two teams, each of the teams reviewed a set of 30 case notes, and members of the teams (apart from two paediatricians) independently reviewed the full set of 30 case notes. The composition of the two teams of reviewers and the protocol is described in figure 19.



Figure 20: Review protocol for Objective 1 (Audit against exit criteria)

The information extracted from the notes was based on the EGAMS transfer (exit) criteria for appropriate management according to risk category in the antenatal, intra-partum and postnatal stages for mother and baby. The proforma that was used is provided in Appendix 10.2. Two teams were recruited, each constituted by an Obstetrician, Paediatrician and Midwife. Members of each team reviewed the same set of notes, but each team had a different set of notes to review.

The proforma used to extract data was first piloted by a Midwife and Paediatrician with amendments made to improve validity and reliability. A user guide was also completed for team members to refer to. Data from completed proforma were input into a Microsoft Access database.

3.2 Internal and external review of mortality and morbidity (Objective 2)

Objective 2 was to undertake an externally validated review of perinatal mortality and morbidity. It was decided that this would be a retrospective review of births at CGH over the five year period from September 2010 to August 2015 inclusive. It was initially proposed that an external group would review the outcomes for the following groups:

- (1) Intra uterine death (IUD) and intrapartum stillbirths after 24 weeks
- (2) Maternal transfers
- (3) Apgar scores of seven or less, five minutes after birth in babies born at Caithness General Hospital
- (4) Neonatal retrievals from Caithness General Hospital
- (5) Early neonatal deaths, that is, deaths during the first seven days after birth

Advice from the Scottish Government was that this review would be best conducted externally using the MBRRACE-UK approach and led by Professor Elizabeth Draper, who had extensive relevant experience. After discussion, the team at the University of Leicester, led by Professor Draper, agreed to review stillbirths, intra-uterine deaths and early neonatal deaths, groups 1 and 5 above. The internal review team agreed to undertake a review of groups 2 - 4. A summary of the external review is provided in Annex 2. The full report has not been appended as it includes extensive identifiable data.

The methodology for review of the remaining categories (maternal transfers, low Apgar scores and neonatal transfers) is provided below. In summary, the aim was to examine a sample of records identified for a range of different reasons, but where there was a higher probability of identifying structural issues with services, should these exist. Maternal transfers were chosen, as it was important to determine the clinical quality of decision making around these transfers. Babies with an Apgar score of less than seven, five minutes after birth represent a group requiring specialist resuscitation skills and it was considered important to assess the quality of resuscitation in these cases. The guidelines in operation in CGH at the time of the death of the baby in September 2015, specified that all infants born with an Apgar score of less than or equal to seven should subsequently be transferred to Raigmore Hospital. It was considered important to assess whether this had happened consistently.

In summary, the review was structured in two parts, with initial independent review of each set of case notes by a small team, followed by multidisciplinary panel review of all cases where an issue had been identified. The following section provides the data sources used and information on how cases were identified.

3.3 Identification of cases

The identification of cases for the different part of the review is outlined below.

3.3.1 Identification of a random set of case notes (Exit criteria audit, Objective 1)

Relevant cases were identified from SMR02 records for the review period (n = 176, 1 September 2014 to 31 August 2015) from which the case notes of a random sample of sixty were obtained. The latter was carried out by using a random number generator (Excel Rand function), ranking the records in ascending order based on a random number, and taking the first 60 cases. There were no critical event cases (stillbirths/IUD or neonatal deaths) occurring during this time period.

3.3.2 Identification of intra-uterine deaths, still births after 24 weeks and early neonatal deaths

Relevant cases were identified from the ISD data sets of SMR02⁵ and SBR (Scottish Birth Records)⁶ and from NRS (National Records for Scotland) still birth and death recording. During the time period four cases were identified (two still births and two neonatal deaths). The original case which was the trigger for this review has not been included in this external review as it had been subject to an SAER. However, in the event the external team undertook to review this case as well.

3.3.3 Identification of cases with an Apgar scores of 7 or less at 5 mins in babies

Relevant cases were identified from the SMR02 data set and the SBR. There were fifteen in the review period (Sept-2010 to Aug 2015 incl.) To ascertain whether these babies had been transferred from Caithness, their records were cross-referenced to neonatal transfer records in the various data sources (Scottish Ambulance Service (SAS); SBR; SMR02 and Caithness log book). Nearly two thirds had been transferred; nine transferred and six not transferred, out of the fifteen low Apgar score babies. It is possible that in some cases mothers declined the offer of transfer to Raigmore, or that the newborn condition improved quickly. However, it would seem unlikely that this was the situation with all six cases.

⁵ The Scottish Morbidity Record (SMR02) is submitted by maternity hospitals to ISD Scotland. This data scheme collects data on inpatient and day case activity in the specialty of obstetrics. A wide range of information is collected, including: mother's age, height, smoking history and previous obstetric history; outcome of pregnancy, mode of delivery, induction and analgesia; and baby's birth weight, gestation, Apgar score and gender. Although there is no legal requirement to submit this data to ISD, the SMR02 data scheme achieves national coverage of 98% of all births and pregnancies. SMR02 is episode based with each admission of a patient generating an individual record about a period of hospital activity. It is possible to attempt to link episodes of maternal care using the CHI number of mothers.

⁶ The Scottish Birth Record was introduced in 2002 as a replacement for SMR11 to record all of a baby's neonatal care in Scotland, from antenatal through to post delivery, including readmissions and transfers in a single electronic record. SBR is based on individuals and events rather than episodes and is completed for all births including stillbirths and home births. The system has been implemented to varying degrees across Scottish hospitals providing midwifery and/or neonatal care.

Conclusion: The fact that six out of fifteen cases with low Apgar scores were not subsequently transferred to Raigmore Hospital in this case note review is of concern. The findings suggest that the staff were not adequately aware of the risks of complications for these babies or perceived a need to keep them in CGH. In either case, clinical need should have been prioritised and the fact that it was not indicates that the model of care in operation at CGH is suboptimal and needs to be revised.

3.3.4 Identification of neonatal retrievals and maternal transfers and from Caithness General Hospital

Maternal transfers and neonatal retrievals from CGH were identified from potentially four sources:

(i) SBR (ii) SMR02 (iii) Book of transfers kept at Caithness General Hospital Caithness log book (iv) Scottish Ambulance Service data of Neonatal retrievals. The details are provided below.

3.3.5 Identification of neonatal Transfers

Neonatal transfers from Caithness General Hospital were identified on SMR02 using the "Baby Discharged to" field (records coded as 4 = transfer to other hospital). If the CHI of the child was not recorded on SMR02 this was populated by matching the CHI of the mother on SMR02 against the SBR maternity record. The transfer date field of the SBR 'Activity Management Report' for Caithness General was used to identify neonatal transfers from the hospital.

During the review period, there were 41 individual neonatal transfers from these records. Crosschecking the SBR and SMR02 records for neonatal transfers identified unique records in each data set (SBR, 7 discordant and SMR02, 9 discordant) although the majority (n = 25) were found in both data sets. This gave concern that transfers might be missed. It was therefore decided that neonatal transfers should also be extracted from other sources to ensure that the review picked up all relevant transfers. In addition, to explore the reasons for the discordant cases between the SMR02 (n=9) and SBR (=7) data sets, the case notes of all of the discordant records were reviewed together with one fifth of the concordant cases (n=5 out of 25).

Neonatal transfers were also identified from the Caithness log book, information from which was keyed into a standard set of data fields of an Access database. All records that involved a transfer of a neonate were included and there were forty nine during the five year review period. Cross-referencing these records with SBR and SMR02 data sets resulted in 38 matches and 11 unique to Caithness log book. Therefore there were 52 records of neonatal transfers as derived from the three data sets.

To ensure that the 52 records were a complete count of all neonatal transfers, a data request to the Scottish Ambulance Service (SAS) was made. This resulted in a list of 41 records of Neonatal retrievals. Inspection of these however identified one case out with the period of the review, four records that were void (both the referring and the receiving unit was assigned as Caithness and non-transfer status was verified on request by SAS), one that recorded the return transfer as well as the outgoing separately and one where the baby was over two months old. Therefore, there were 34 neonatal retrievals recorded by the SAS data source. Of these, 30 were matched to a neonatal transfer record on SMR02/SBR and 32 of them to a transfer on the Caithness log. Between the SMR02 and the Caithness log data sets there were no records unique to the SAS data set.

As the number of cases identified was larger than we could review, it was decided to restrict the number of neonatal transfers to be reviewed based on clinical criteria. We would expect all cases where the gestation was less than 37 weeks or where the foetus was known to have low birth weight to be transferred. There seemed little to be gained by reviewing these cases. A decision was therefore made to restrict review to those cases where gestation was 37 weeks or over and the birth weight was 2.5 Kg or greater. The restricted criteria were applied using fields in SMR02 and where necessary, SBR data as the source of birth weight and gestation. A sub-set of 33 cases of the 52 cases met these inclusion criteria (figure 20).



20a: From SMR02/SBR



3.3.6 Identification of maternal transfers

Maternal transfers were identified from SMR02 by selecting 'maternal discharge/transfer to codes (40-5G) that provide detail of transfer within Board and to other Health Boards and Health Care

Providers. Further analysis was done to identify the hospital at transfer by using the CHI of the mother and the dates of admission and discharge on both SMR01 (Acute inpatient and daycase data) and SMR02 recording. During the review period, Sept 2010- August 2015 inclusive, there were 105 recorded maternal transfers. Information from the written records in the Caithness book of transfers was also input into an Access database. Each of the transfers were categorised in respect to maternal transfers status as:

- Pregnancy booked at CGH, any transfer stage (other than postpartum or neonate unwell), any transfer mode, delivered at Raigmore Hospital or other hospital-*true maternal transfer*
- Pregnancy booked at Raigmore Hospital, at antenatal or intra-partum transfer stage, any transfer mode, delivered at Raigmore Hospital-*false maternal transfer*
- Any mothers transported to another hospital due to unwell neonate- false maternal transfer
- Pregnancy booked anywhere, postpartum transfer stage, any transfer mode, reason stated as unwell mother- *true maternal transfer*

Some of the records had insufficient details to allow the transfer status to be deduced. This in the main applied to the hospital of booking. For such cases, cross-referencing to SMR02 data using CHI of mother allowed imputation of the place of booking. In addition, where there were twins, the hospital of booking was taken as Raigmore. There were however some cases where the transfer status was indeterminable. There were 215 maternal transfers during the review period and these, according to the application of the above criteria (1 to 4), and cross-reference with data from SMR02 data broke down as follows (figure 21).



Figure 22: Maternal transfers as identified from the Caithness Log

There were 94 records of maternal transfers from the Caithness Log; (50 are matched with SMR02, 44 unique to Caithness Log, see figure 3) and a further seven unique to SMR02, (105xSMR02 records – 98 cases of Caithness log-matched records) making a total of 101 maternal transfers for review (figure 22).





In order to identify a representative sample of these maternal transfers to review, the records of 'true maternal transfers' as defined from the data in the Caithness Log (n = 94), were categorised into groups according to the reason given for transfer (table 12).

Table 12: Maternal transfers by category of reason given in the Caithness Log and identification of the sample of records to be reviewed

		ctual	ual To revie	
Reason category ¹	Count	% Count ²	Pro- rata	Agreed
Pre-term labour (<37 weeks) with contractions, intra- partum transfer	42	45%	12	12
Pre-eclampsia (high blood pressure, oedema) and Eclampsia	14	15%	4	4
SRM <37 weeks with or without contractions	13	14%	4	4
Significant APH (ante partum haemorrhage)	7	7%	2	2
Mother unwell	5	5%	2	2
Foetal issues e.g. diminished movements; need for CTG	5	5%	2	2
SRM >37 weeks and not in labour after 24 hours, transfer for induction	4	4%	1	4
Maternal request for epidural	2	2%	1	0
Induction of labour	2	2%	1	1
All above	94	100% ³	29	31
Unique SMR02 maternal transfers	7	-	7	7
Grand Total	101		36	38

Source: review of the data extracted from the Caithness Log of transfers; ¹transfer reason as provided in the Caithness log of transfers; ² Percentage of the Caithness log transfers (n=29). ³ This total adds up to 99% due to rounding errors.

Of the total number of transfers (n = 101) it was considered that one third should be reviewed (n = 36), as the review team did not have the capacity to review a larger number. It was considered that this would give a reasonably statistically robust estimate.

Of the 36 transfers, seven were unique SMR02 records for which we did not have the reasons for transfer without looking at the case notes. Therefore all of the SMR02 unique records were reviewed together with the remaining 29 cases for which there was a reason provided for transfer. To make the sample representative in terms of the different types of reason for maternal transfer, selection of the 29 cases was undertaken, based on the relative frequency for the different reasons for transfer. However, the Technical Review team discussed the pro-rata sampling by category and agreed that all cases with an SRM occurring at term in women at gestation of 37 weeks or greater should in total be reviewed (n = 4). This was based on the fact that the index neonatal death, which triggered this review, occurred where there was 'prolonged rupture of membranes' in a term infant. The review team considered it important to assess whether this was a pattern observed in other cases.

It was also agreed that there was no need to review the category comprising maternal requests for epidurals, as it was unlikely that lessons would be drawn from such cases. These requests automatically generate a transfer to Raigmore as CGH unit do not undertake epidurals. Table 12 lists the 38 maternal transfers where case notes were reviewed.

3.4 Reviews of identified cases

3.4.1 Review of random set of case notes (exit criteria audit)

Following identification of CHI numbers as outlined above, case notes for the two sets of thirty births were extracted, scanned and copied to encrypted memory sticks by the Medical Records Department based at Raigmore Hospital. These were sent to the reviewers with passwords issued separately. Each case was reviewed, using a proforma, by a member of each of the two review teams, each team comprising of three members. The proforma is provided in Appendix 10.2.

The results were inputted to an ACCESS database and an initial analysis undertaken to provide a rate of births where there was a finding of inappropriate or suboptimal management according to an agreed set of criteria. This was based on negative answers to the questions in sections 6.3 and/or 6.6 of the proforma, "Was the overall care appropriate at this stage?"

Cases where one or more of the three reviewers identified inappropriate or suboptimal management were retained for further review by a multi-disciplinary panel (see section 3.5).

3.4.2 External review of intrauterine deaths, still births and early neonatal deaths

The case notes of the mothers (n = 5) and in the case of the neonatal deaths, those of the babies as well (n = 3), were extracted, scanned and sent by encrypted memory stick to the external review team (Leicester) for external review.

3.4.3 Internal review of neonatal transfers, selected maternal transfers and babies with low Apgar scores

The overall aim of the review of these cases was to test whether the process of risk assessment and clinical decision making was clinically appropriate in relation to guideline-defined conditions. The guidelines in question were those in operation at CGH at the time of the death of the death of the baby in September 2015. This was as a measure of quality and standard of care for example in neonatal transfer⁷.

Proformas were devised locally that could be used to review cases, based on appropriate criteria, and an assessment as to whether or not: the transfer decision was appropriate; the timing of transfer was appropriate; and whether the outcome was satisfactory. The proforma was developed from assessment of tools identified by online searching. The following tools were identified and reviewed:

- MBRRACE-UK
- Healthcare Improvement Scotland (HIS) Scottish Programme for Clinical Effectiveness in Reproductive Health (SPERCH)
- IHI Global Trigger tool
- NEWTT framework and data collection tool

The proformas that were subsequently utilised drew on all of these tools. Maternal and infant case notes were reviewed by an Advanced Neonatal Nurse Practitioner (ANNP) and the Project Midwife.

A prototype proforma was piloted on a sample of three cases from each of the three categories (maternal transfers, neonatal transfers and low Apgar scores) by a paediatrician and senior midwife and changes made before its application to all of the cases. The final proforma (see Appendix 10.3) was based on the following criteria:

(a) Low Apgar scores OR neonatal transfer

Known at 4 hours or later after birth for all births and the neonate should be transferred where:

- Cord pH ≤ 7.1
- Low blood sugar < 2.6 mmoles/I @ 2 readings
- Temperature < 36.5°C or ≥ 38.0°C
- Oxygen requirement or CPAP
- Signs of sepsis
- Respiratory distress

(b) Maternal transfers

Known at intrapartum or postpartum:

- Infection of uterine membrane (chorioamnionitis)
- Abnormal CTG
- Intrapartum / postpartum haemorrhage
- Pre-eclampsia
- Eclampsia

⁷ Fenton A C, Leslie A, Skeoch C H, Neonatal transport services: Optimising neonatal transfer. *Arch Dis Child* Fetal Neonatal Ed 2004;89:F215-F219 doi:10.1136/adc.2002.019711.

Cases where inappropriate or suboptimal management were retained for further review by a multi-disciplinary panel (see section 3.5).

3.5 Full panel review of potentially significant cases

A multidisciplinary team comprising two midwives, one ANNP, a paediatrician, an obstetrician and a chair (Director of Public Health) meet on the 9 August 2016. Originally, an external obstetrician was due to attend, but unfortunately, none were available. The aim of the full panel review was to assess whether there were any patterns or common characteristics across the cases and whether any lessons could be learned.

A proforma (see appendix 10.4a & 10.4b) was designed for the panel to review these cases addressing the following issues:

- Description of the issue/problem
- What should have been done to minimise the risk to mother and/or baby?
- What needs to be done to avoid it happening in the future?
- If CGH had been a midwife-led unit, would the problem have arisen? (The degree of likelihood was categorised)

The proforma was pre-populated for each case in terms of the description of the issue/problem that had been identified according to the initial screen. Completed proformas from the initial review of case notes were also provided as were the full medical records. Caldicott Guardian approval was sought for the review.

The results of the review are presented in section 4.

3.6 Issues of data quality

This review uncovered a range of data issues. These are summarised below.

3.6.1 Maternal transfers

There were potentially two data sources for identifying maternal transfers: SMR02, and the Caithness log book.

SMR02 itself does not provide the hospital from which a transfer occurred. In order to establish this, the SMR01 (Acute) data set was required. Matching the CHI of the mother and the dates of admission and discharge, the SMR01 was used to assign the hospital transferred from and thence capture all those occurring from Caithness General. Once this was done there were 105 records of maternal transfers during the review period. However, only 93% (98/105) of these could be matched to those recorded in the Caithness log.

The Caithness log, which was hand written, had 215 recorded transfers with less than half of these (n = 98) matching SMR02 records. Due to the mis-match between these two data sets, it was not possible to identify whether the SMR02 data set was incomplete (less than 50% complete) or that the Caithness log was recording some transfers that were not "true" maternal transfers. By application of a set of criteria to the Caithness log, less than 50% of the latter were then defined as transfers. The final count between the two data sets was 101 transfers but only 50 of them were matched between them leaving almost the same number unique to the Caithness log and seven to SMR02.

In conclusion, the SMR02 data set may be missing coding of maternal transfers by around 50% and the Caithness log 7%.

3.6.2 Neonatal transfers

There were potentially four data sources to identify these: SBR; SMR02; Caithness log; Scottish Ambulance Service.

Using the transfer data field of the SBR 'Activity Management Report' for CGH identified 32 transfers, 25 of these matched a transfer identified via SMR02 leaving seven unique transfers to this data set. Using the "Baby discharged to" field, there were 34 transfers identified from the SMR02 data set. The Baby CHI number where not completed, required cross-checking using the maternal CHI with the SBR data set for its acquisition. There were 25 matching transfer records between SMR02 and SBR, leaving nine unique to the SMR02 data set. Using the SAS spreadsheet, there were 34 neonatal retrievals recorded during the review period, of these, 30 matched SMR02/SBR records and 32 matched a Caithness log transfer. There were no unique records in the SAS data set. Using the Caithness log, 49 neonatal transfers were identified and of these, 38 matched with SBR/SMR02 transfers leaving eleven unique to the Caithness log. All data sets together identified 52 records of neonatal transfers.

To establish the validity and uncover any explanation for the discordant transfers recorded on SMR02 (n=9) and SBR (n=7), the case notes of all the discordant cases together with a sample of matching cases were reviewed. The case notes verified that seven out of the nine discordant SMR02 records had been neonatal retrievals. The mode of transport of the other two could not be ascertained. Six out of the seven discordant SBR records were found to have been neonatal transfers with the remaining one transferred by road ambulance. The SBR/SMR02 discordant records with only one exception matched a neonatal transfer record in the Caithness log which suggests that these discordant records were valid.

In conclusion, the SBR and SMR02 data sets did not match and together they made up 39% (16/41) of the pooled number of transfers. Under-recording was 38% ((52-32)/52) for SBR and 35% ((52-34)/52) for SMR02.

3.6.3 Low Apgar scores at 5 minutes

These were identified from the SMR02 data set. The degree of completeness and accuracy could not be ascertained as there was no alternative data source. However there was one instance where a low Apgar score had been recorded on the SMR02 data set but not on the case notes where it was higher than 7.

Conclusion: There is a need for regular data cleaning of maternity and neonatal datasets to allow effective audit of care across a 'hub and spoke' model involving shared care between Raigmore hospital and peripheral units.

4 Results of the Review

The results of the initial review of case notes are presented below.

4.1 Compliance with exit/transfer criteria in the random set of case notes

As previously described, the case notes of the two sets of thirty births were extracted and reviewed completely by a member of each of the two teams, each team comprising of three members.

Out of the sixty births, thirteen cases (22%) were reported to be associated with suboptimal or inappropriate care for the baby or the mother. Four of these cases were identified as such by two or all three members of a particular team whilst the remaining nine were identified by only one reviewer.

Conclusion: Suboptimal or inappropriate care was identified in 22% of case notes that were reviewed. A review of cases in any hospital would be expected to identify some cases of suboptimal care, but is higher than might have been anticipated in a high performing service.

4.2 Review of other groups of cases

As previously stated, several sets of maternal and infant case notes were reviewed by an Advanced Neonatal Nurse Practitioner (ANNP) and the Project Midwife and brought to a multidisciplinary panel. There were some exceptions. Two of the three cases identified as having low Apgar scores were not sent for further review by the panel. In one case this was because the case notes indicated that the SMR02 record stating that the Apgar score was low had been incorrect. In the second case, the outcome was a neonatal death and the case was being reviewed by the external Leicester team. The results of the review are summarised in figure 23 below.

Figure 24: Categories of cases identified where there was suboptimal or inappropriate care

	CATEGORIES					
	Maternal Transfers	Neonatal Transfers	APGAR ≤ 7	EGAMS Review		
Parent Group	101	52	15	163		
Sample	38 selected ¹	33 selected ²	13 selected ³	60 selected⁴		
Initial assessment	3 issues	3 issues	1 issue	13 issues		
Panel review	3 issues	3 issues	1 issue	8 issues		
Overall issue rate	8%	9%	8%	13%		

¹one third sample was taken which was proportionate in terms of the relative frequency of the types of reason for transfer except for SRM \geq 37w with no labour<24h which was 100% represented, none were selected due to women's wish for epidural.

²these were all the transfers of neonates with birth time \geq 37 weeks and weight \geq 2.5Kg

³examinaton of all 15 low APGAR scores as per recorded on SMR02 showed one to have died and therefore was to be reviewed by the external review team in Leicester, another did not have low Apgar scores and was being reviewed as a neonatal transfer

⁴Randomly selected births from all births (no still births or neonatal deaths) at Caithness General occurring during the 12 month period 1st September2014 to 31st August 2015

Out of twenty cases originally identified with possible issues in respect of their care and/or management, the review panel confirmed that fifteen gave cause for concern. The reasons agreed by the panel were themed into ten different but non-mutually exclusive categories. These are shown with a breakdown by category of case (figure 24).

Figure 25: Results of panel review: types of reason given for cases (n = 15) considered to have issues in their care and/or management with breakdown by category of case reviewed



Note: The reasons are not mutually exclusive and a case can be associated with several types of reason

An example of a situation in the cases reviewed in which the finding of the panel was management out with guidelines is presented as a vignette below.

Case study (some details have been changed to preserve anonymity)

A pregnant woman was admitted to CGH some weeks before her baby was due to be born with symptoms of a common but serious condition that occurs in the later stages of pregnancy. She was monitored for some time, but developed features that suggested that her condition was getting worse. Eventually she was transferred to a better equipped hospital where additional treatment was initiated.

View of the panel

Although there was no adverse outcome for the mother or baby, the review panel were of the view that optimal treatment would have involved earlier transfer to a better equipped hospital. There was some risk that if the condition had deteriorated further, the mother or the baby could have experienced avoidable harm or could even have died.

There are clear patterns to the problems identified at CGH that are consistent with structural issues associated with an EGAMS 2a unit. There was a recurrent pattern of treatment outside normal guidelines, an apparent lack of awareness of the neonatal implications of management plans for the mother, and missed opportunities for earlier transfer to Raigmore Hospital. The view of the authors is that the continued use of an EGAMS 2a model is not a safe in the context of CGH.

4.3 Impact of care in a CMU

For each case, the panel considered whether the problems in the management and/or care would also have arisen if it had been a CMU as opposed to an EGAMS 2a unit without paediatric support. The panel decided that the majority of cases (two-thirds) would not have arisen in a midwife-led unit, over one tenth (13%) where it might have been possible and one fifth where it could equally have occurred. There were no cases where the panel believed that the problem would have been more likely to occur at a CMU (table 13).

	Degree to which the problem would have arisen in a				
	midwife-led unit				
Type of case	Unlikely	Possi	ble	Equally likely	/ More likely
Maternal transfer		3	()	0 C
Neonatal transfer		3	()	0 C
Low Apgar score		0	()	1 0
Out with EGAMs criteria		4	2	2	2 0
All	10 (67	7%)	2 (13%) 3 (20%) 0(0%)

Table 13: Review Panel's ratin	of the likelihood of the issues	arising in a midwife-led unit

Source: Panel Review completed proforma (09/08/2016)

Conclusion: The review panel believe that an EGAMS 2a unit has structural weaknesses that engender sub-optimal care and that in the Caithness context a CMU provides better care for mothers who are classed as being at 'low risk'. This is largely because CMUs are not designed to observe cases for extended periods of time, i.e. if labour is not established mothers are sent home and if risks are emerging, mothers are transferred to an appropriately staffed centre.

4.4 External review of the early neonatal deaths and stillbirths

The external review assessed each of the five case to give a final grading on the care received, according to the following criteria:

Sub optimal	Definition
care grade	
0	No sub-optimal care
1	Sub-optimal care, but different management would have made no difference to the outcome.
2	Sub-optimal care in which different management might have made a difference to the outcome (i.e. an avoidable factor of uncertain influence on outcome).
3	Sub-optimal care in which different management would reasonably be expected to have made a difference to the outcome (i.e. an avoidable factor that contributed to a poor outcome).

The results of each case is summarised in below.

Case 1	Grade 3 - Sub-optimal care in which different management would reasonably be expected to have made a difference to the outcome
Case 2	Grade 2 - Sub-optimal care in which different management might have made a difference to the outcome
Case 3	Grade 3 - Sub-optimal care in which different management would reasonably be expected to have made a difference to the outcome
Case 4	Grade 2 - Sub-optimal care in which different management might have made a difference to the outcome
Case 5	Grade 2 - Sub-optimal care in which different management might have made a difference to the outcome

Professor Draper's review concluded that the death of a term baby in September 2015 exemplified the limitations of the care that can be provided to babies born in CGH. Her team found that in all the deaths they reviewed that there was evidence of suboptimal care. They found that whilst some improvements to care of newborns could be delivered through additional practice measures, many of which have been put in place since September 2015, ultimately, very serious conditions can present with subtle signs. Therefore involving appropriate specialist staff (such as paediatricians) at an early stage is a more effective way to prevent further serious incidents, as opposed to additional training for staff.

The team conclude by noting that: 'in relation to obstetric and midwifery care the service at Caithness appears (in relation to these cases) to operate to a satisfactory standard. However the geography and the nature of the staff available set limits on what can be provided without transfer. It is important that these limitations are made clear to women who book at this unit.'
5 Discussion

NHS Highland is faced with the challenging task of providing high quality maternity and neonatal care across the largest geographical area of any health board in Scotland. In doing so, it strives to balance patient safety, efficient use of workforce resources and public and user's expectations of healthcare provision.

The remit given to the Public Health review group was to consider the safety of neonatal care provided in Caithness General and to make recommendations for the future configuration of maternity and neonatal care. In order to do this, the review group has looked at the current evidence, literature, guidelines and practice, and reviewed maternal and neonatal case notes. The results of both internal and external review have been provided. This discussion pulls together the main themes from these results in order to reach conclusions about the safety of the current service and to make recommendations for a future model.

5.1 Antenatal services

Antenatal care for all pregnant women is co-ordinated by the midwifery teams. Low risk women do not need to see an obstetrician but high risk women require regular reviews and care planning by the obstetric team. High risk pregnancies are associated with greater intrapartum and neonatal interventions and require booking for place of birth in a Level 2c maternity unit (EGAMS, 2002). In relation to future service, this means that there is an identified need to have local obstetric input to antenatal care to prevent additional travel for women and families to Raigmore for obstetric antenatal checks; this is in line with current obstetric services to other NHS Highland remote and rural areas and CMUs. The annual workload activity at CGH in terms of new and follow-up obstetric outpatient numbers just prior to the death of the baby in September 2015, equates to just under 5 consultant hours per week (assumes 30 minutes per new patient and 15 minutes per return patient and 44 working weeks per annum). This translates to 1.25 consultant sessions per week and this level of service is expected to be required in any future redesign of the maternity facility in Caithness. A strong case can be made for providing this input via a 'hub and spoke' model including weekly visits from Raigmore Hospital.

Conclusion: The care of antenatal women living in Caithness and Sutherland would best be met by a 'hub and spoke' model, with a hub at Raigmore Hospital and a local midwife-led CMU.

5.2 Intrapartum Services

When we consider intrapartum services, we know from published evidence that approximately one third (33%) of pregnancies will be eligible for birth in a CMU (RCOG 2013). The Royal College of Obstetricians and Gynaecologists (RCOG) report indicates that 17% of pregnancies are 'high risk' and 50% are classified as 'unknown risk'. One quarter of the latter group will require step-up care prior to labour (e.g. due to foetal growth restriction) and 40% will require transfer during labour.

5.2.1 Patient Flows - Model 1

In 2014/15, there were 264 births from women resident in the Caithness district of which 161 occurred at CGH and 92 at Raigmore Hospital. Rounding this annual birth rate up to 270, and based on the data in the RCOG report, we would expected 90 low risk births to be booked at a

CMU in CGH, of which five (5%) could be expected to require step up care. Just under one fifth (17%) would be expected to be booked at Raigmore (n = 45). The remaining 135 pregnancies would be of 'uncertain risk'. Again according to RCOG, one quarter (25%) will need step-up antenatal care and 40% transferred in labour to level 2c maternity facility (Raigmore). In summary, during one year one would expect around 84 planned births at Raigmore either at booking or later during pregnancy and 85 low risk births booked at a CMU. A further 61 of the 135 uncertain risk births would be expected to go on to be delivered at a CMU and one would expect 40 cases to be transferred in labour to Raigmore. Therefore at Raigmore there would be 124 births, 40 of which would be intrapartum transfers. This equates to an extra 2.6 deliveries per month at Raigmore (92-124 per annum) with a doubling of the current intra-partum transfers, from 20 to 40 per annum. Figure 25 depicts these flows.

Figure 26: Anticipated patient flows between a CGH CMU and a level 2 facility, based on RCOG data



Source: based on RCOG 2013 report

5.2.2 Patient Flows - Model 2

However, in practice significantly fewer pregnancies of uncertain risk would be booked at a CMU, in line with the current practice across NHS Highland where almost one half would be diverted to level 2c care prior to labour. This reflects the local exit criteria, which are to achieve a lower risk at CMUs in the situation where there is over a two hour travel time to Raigmore Hospital. Those affected by the stricter criteria will mainly be primigravidae. Using these criteria, a locally expected flow between a CMU in Caithness and Raigmore is described below.

The average percentage of births to primigravidae who are Caithness residents is 41% (average over the most recent five year period 2011/12 to 2015/16 according to SMR02 data). When applied to the 101 pregnancies of uncertain risk, one would expect an additional 41 primigravidae to be diverted to Raigmore Hospital. Of the remaining 60, 40% (n = 24) could be expected to require intrapartum transfer. This would mean 121 annual births in a Caithness CMU compared to

146 on the basis of the RCOG algorithm. Raigmore would undertake 149 deliveries, 24 of which would be intra-partum transfers. See figure 26 below.





The overall increase in the numbers of births at Raigmore given a CMU model in place in Caithness (from 92 to 149), see section 5.2.1) would be equivalent to 2.9%, assuming an average annual number of births of 2,000 (57/2000). This is only an estimate as the total number of births at Raigmore can vary by as much as 200-300 up or down per year. Workforce and resource issues would require to be addressed if the additional workload from Caithness was to become a permanent change in service provision. Changes should be made in line with national standards for the provision of workforce skill mix (Sandall *et al.*, 2014; RCOG 2014; RCM 2009).

Transfer rates are approximately 20 maternal per annum equating to 12% of the 165 births at Caithness General. In a future CMU model, we may expect a slight increase (from 20 to 24, see figure 26) There are currently 10 neonatal transfers per year. We would expect this rate to fall with a CMU model in place.

A summary of the possible changes in annual numbers of births and transfers should a CMU model replace the current service is provided in the table below:

Table 14: Possible annual numbers of births and transfers relating to Caithness residents according to type of maternity service model

	Maternity Service model				
	EGAMS 2a	EGAMS 2a Community Maternity Unit			
	Current service	Model 1 (RCOG)	Mode	2 (Local exit crteria)	
Births at Raigmore	10	5	124	149	
Births at Caithness	16	5	146	121	
(*Total births	27	0	270	270)	
Intrapartum transfers	2	.0	40	24	
Neonatal transfers	1	0	<10	<10	

*Assumed annual number rounded up from the 264 actual births occurring in 2014/15

Any permanent change to Caithness maternity services that reduce the workload in Caithness will impact on the midwifery team's intrapartum skills and this needs to be taken into account when planning the future model (Tucker *et al.*, 2005 and 2008).

Conclusion: Although the introduction of a CMU at CGH would increase maternal transfers, it would decrease neonatal transfers and provide further reduction in neonatal deaths.

5.3 Challenges presented by the current model

The current model of maternity care in Caithness is a Level 2a EGAMS which means that it has a Consultant-led obstetric service without the local support of paediatricians, a special care baby unit (SCBU) or an adult high dependency unit (HDU). In practice, this creates a structural driver for inappropriate care, as obstetric services can be provided for mothers, but an equivalent service cannot be provided for their babies. The low volume of deliveries also makes it very difficult for obstetricians to maintain adequate exposure to key procedures and maintain competence. A small remote group of obstetricians also risks professional isolation, which can adversely affect the quality of care.

Staff in the CGH maternity unit are dedicated and hard working and nothing in this report is intended to be a direct criticism of the staff. We believe that this is a structural issue, where sub-conscious drivers operate to produce scenarios where suboptimal care is more likely to occur.

5.4 Clinical Decision Making and risk assessment

Consistent with the finding of the external review, the review of case notes showed that EGAMS 2a model leads to some mothers with increased risk factors remaining in the local service when transfer would have been optimal. The 15 cases identified where there was an opportunity for earlier transfer to Raigmore in 12/15 is in line with findings of the 2005 national review of CMUs in Scotland (Hogg *et al.,* 2005), which included Orkney and Shetland (Level 1c maternity units with medical support). The national review showed that of the 526 (31%) women identified as 'higher risk' using the EGAMS criteria, 86 (16%) were transferred (Hogg *et al.,* 2007:p36), the remainder remaining within the local services.

Overall, this review comes to the conclusion that the current obstetric Level 2a model in Caithness has an impact on the decision making about place of birth and that this increases the risk to mothers and neonates, health professionals and the organisation. The risk is that continuing with the consultant obstetric model blurs the boundaries between acceptable practice in a CMU versus a consultant-led unit. This can lead to local management of more complex obstetric problems than would be delivered at comparable CMU units (e.g. Fort William or Broadford). Furthermore, mothers might choose Caithness as their place of birth in the knowledge that there are consultant obstetricians available, while not fully appreciating that there was no neonatal support and the risks that this poses for their baby. This conclusion is supported by the external review team report.

The management of high risk cases in the absence of neonatal paediatricians can contribute to poor communication and differences of opinions between professional groups when potentially life and death decisions have to be made within a compressed timeframe. This is perhaps reflected in the fact that in 11/15 cases there could have been better teamwork and leadership.

5.5 External review of team and organisational culture and leadership

A visiting team spent a day in CGH (18 May 2016) in discussion with the Lead Midwife, the Senior Charge Midwife, members of the Midwifery Team, the Managerial Lead, the Clinical Lead, an Anaesthetist and a Sister from Theatre. A second day (19 May 2016) was spent in Raigmore in discussion with the Midwifery Manager, Advanced Neonatal Nurse Practitioners (ANNPs), Senior Charge Midwives from the antenatal labour ward and neonatal unit, Paediatricians, Obstetricians and the Director of Public Health for NHS Highland.

In relation to teamwork and organisational culture, the external team made the following observations:

- The Caithness midwifery team were enthusiastic and motivated and strong sense of team
- Midwifery staff currently provide neonatal care, supported by local medical staff and advice from Raigmore via telephone and videoconference links
- Support for out of hours neonatal and maternity services at Caithness General was traditionally provided by local anaesthetic staff. However, these posts are now often filled by locums who may not have neonatal resuscitation and stabilisation skills. Increasing specialisation of medical specialists also means that the right expertise is not always available.
- Paediatric Consultants in Raigmore have concerns about complex clinical decision making at a distance and question the current service model.
- There are good telephone and teleconference facilities and these are used for daily and weekly safety briefs
- ANNP support for training in Caithness on a monthly basis is highly valued
- Overall, the external review team concluded that maternity and neonatal care at Caithness General should be on the basis of a CMU

5.6 The views of service users

This review has focussed on the clinical safety of neonatal services in CGH and has based its risk assessment and decision making on that basis to minimise harm when complications arise. It is recognised that no model is risk free and that women and communities have different perception of balance of risk and what is important when making choices about their planned place of birth (Barclay *et al.*, 2016: Cheyne *et al.*, 2012). It is important to recognise that such women have the choice to give birth at Caithness General, even if they have been advised against this on a clinical basis. However, NHS Highland cannot make a decision to provide a service where the level of safety is at risk of being below a nationally acceptable standard. This review concludes that the ongoing provision of high risk obstetric procedures in Caithness poses a risk of that nature.

An initial objective of the review, objective 5, was to assess the feasibility of using health economics techniques to understand better the views of mothers in remote and rural settings. Discussions with the Health Economics Research Unit (HERU), Aberdeen University has confirmed the feasibility of such an approach to better understand maternal preferences. It is intended to carry out a study to examine the views of pregnant women and mothers in relation to the potential risks and benefits that are important to them when coming to a decision about where to give birth: what factors influence women's decision making when they live at a distance from access to full obstetric and neonatal services. This work may be of use to an implementation group.

5.7 Equality Impact Assessment

The main impact that the conclusions of this report will have is a reduction in the number of local births. This impact will be reduced as the Caithness maternity service has been working to interim risk measures since September 2015 and therefore many families have encountered this change already. An equality impact assessment has been undertaken in relation to protected characteristics. This has not identified any factors that would change the conclusions of this report.

5.8 Comparative work

The review did not have the capacity to undertake comparative review of other maternity units across NHS Highland. Previous work in this field which assessed appropriateness of risk assessment in CMUs in Scotland showed that women were referred appropriately for obstetric and other specialist care (Hogg *et al.*, 2007; Tucker *et al.*, 2010). Nationally, work has been done recently on low risk births in England and Wales (Brockelhurst *et al.*, 2011) but this did not look closely at specific challenges for remote and rural units. Barclay *et al.* (2016) and Grzybowski *et al.* (2011) have published on the challenges of distance in provision of maternity care in Australia and Canada respectively. Further work in relation to the management of risk and appropriateness of care in remote and rural maternity and neonatal services could be undertaken in the future.

5.9 Model of care scenarios

Before reaching a conclusion on the future service provision, the review team considered the other models of maternity & neonatal care that that could be taken into account.

Scenario	Reasons for rejection
Retain the current model with full time planned and out of hours (OOH) obstetric support	Limited volume of work and maintenance of consultant skills.
	Puts babies at risk of harm.
	Undertaking caesarean sections in the absence of an adequate adult HDU facilities could put mothers at risk.
Full time planned and OOH neonatal paediatric support	This would require several fulltime paediatricians to cover 24 hours per day 365 days a year.
	The workload would be so small that staff could not adequately maintain skills.
	It is unlikely that recruitment would be possible.
Full time planned and OOH Advanced Neonatal Nurse Practitioner (ANNP) support	This would require several fulltime ANNPs to cover.
	This would only provide cover for some scenarios and arguably could increase a false sense of security, encouraging inappropriate retention of cases and putting babies at risk.
	This would not adequately reduce risk in the absence of a fully staffed Neonatal Intensive Care Unit.
	The workload would be so low that such staff would struggle to maintain competence across an adequate range of clinical scenarios.
	Recruitment and retention of staffwould be challenging.

None of the scenarios provided in the above table provide a better solution than a CMU as part of a 'hub and spoke' model of care, with clear seamless pathways of care.

6 Conclusions

The internal components of this review lead to the conclusion that the population of Caithness and Sutherland would best be served by a CMU in CGH. This conclusion is consistent with the two external reviews.

The findings of the external independent enquiry into five perinatal deaths identified elements of sub optimal care in all the cases. The report highlighted the need for effective channels of communication between Raigmore and CGH, ensuring that senior staff are involved is providing advice at an early stage in any emerging problems.

With regard to access to care and accommodation for women and families in Raigmore, the external review identified that travel to Raigmore and issues with limited social accommodation for women and their families had an impact on care, particularly when combined with psycho-social factors and women in vulnerable situations. The external review report suggested that family-centred facilities in or near Raigmore Hospital could ease the social impact of changes to service configuration.

In order that women can make an informed choice about their care and place of birth, the external reviews recognised that women should be given clear information about the level of service available at CGH and the limitations with regards neonatal care and adult high dependency care. Topic specific information sheets should be shared with women, discussed, and an agreed place of birth should be documented.

6.1 A Hub and Spoke Model of Maternity and Neonatal Care

There is no doubt that geographical distance and potential professional isolation create challenges for the safe provision of maternity and neonatal services across NHS Highland. The transfers examined through the review indicate the levels of risk involved and the complexity of distance, time and travel.

Given these clinical complexities, it is incumbent on NHS Highland to put in place systems and processes that enable clinical services to operate as smoothly as possible. This review concludes that a safe model of maternity and neonatal care for women, neonates and families, and maternity care professionals can best be provided through effective team working involving a 'hub and spoke' model for maternity and neonatal services across NHS Highland, which effectively supports a CMU in CGH.

While the focus of this review has been on Caithness, the evidence make it clear that a small remote maternity unit within a small hospital cannot operate safely on its own and therefore NHS Highland should strengthen the Highland wide maternity and neonatal clinical and managerial leadership, based on a 'hub and spoke' model, with a flexible workforce deployed across the NHS Highland area. This should include an approach to developing better joint working between Raigmore, local CMUs and community midwifery teams.

Triage should be in place to ensure that midwives working in Caithness (as in other CMUs) can escalate care to the on-duty obstetric and neonatal paediatric staff and senior midwifery staff in Raigmore. There is a need to clarify who takes responsibility for the onsite medical care. This

should include clear guidance in relation to the role of the distant specialist obstetric and neonatal team in the Raigmore hub; and the local support given by anaesthetic teams and emergency response teams.

The need to maintain clinical skills when workload is low is a challenge that is faced by the service and recognised as an influencing factor in both the external reports. There is a need for flexibility within the workforce and opportunities for shared working across sites in order to facilitate clinical skills maintenance and updating and to share clinical practice across the Health Board. To this end, clinical and service leadership is required. Opportunities for staff in CMUs to work in Raigmore should be strengthened across NHS Highland. This could include Highland wide posts with responsibilities in Raigmore and peripheral units.

The use of regular multi-disciplinary huddles/safety briefings provides an opportunity to share clinical concerns, develop clinical management plans, escalate problems, and work as a close team across maternity and neonatal care. Such arrangements are in place and should be continued and strengthened.

It is recommended that a senior clinical team comprising Obstetric, Paediatric and Midwifery staff is convened to consider the clinical practice issues that have been highlighted in this report and to consider how these are to be addressed within NHS Highland maternity and children's services.

Professional leads should continue to ensure that guidelines are regularly reviewed, brought up to date, shared, easily accessible and version controlled. Critical incidents should continue to be discussed regularly and systems to report and escalate clinical events should be in place (risk meetings, perinatal etc).

In relation to service improvement, the introduction of electronic maternity records would support the easy transfer of, and access to, important clinical documentation for maternity and neonatal care professionals in Raigmore and CGH.

The model of maternity and neonatal care for NHS Highland should include the regular use of videoconference/telehealth links and e-documentation as part of everyday practice and core to the model of service delivery.

There is a need for closer liaison with ambulance and neonatal retrieval services to ensure that these services can provide timely responses even when several cases require attention in relatively rapid succession. This needs to be based on a statistical understanding of the stochastic nature of such events, or as is colloquially observed, "Busses often seem to come in threes".

7 Recommendations

Recommendations

This report makes two recommendations:

1. Caithness maternity unit should become a midwife-led CMU in line with the model of maternal and neonatal care in other parts of NHS Highland. This change is designed to improve the safety of both neonatal and intrapartum care for the population of Caithness and Sutherland.

2. Strengthen the hub and spoke model of maternal and neonatal care across the North Highland Health and Social Care Partnership (HHSCP). This approach would strengthen Raigmore as a hub, providing 24 hour per day obstetric, midwifery and neonatal support to all the CMUs and community midwifery teams across the HHSCP. Obstetric, midwifery and neonatal staff based at Raigmore Hospital would support all the spokes in the model, including Caithness and Sutherland.

This model will require additional leadership by clinical and managerial staff, greater use of communication technology, ready access to homely accommodation for mothers and families who may have to stay near Raigmore hospital, and closer liaison with ambulance services and neonatal retrieval services to ensure a seamless pathway of care.

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9 Glossary

- AMU: Alongside Midwifery Units
- ANNP: Advanced Neonatal Nurse Practitioner
- Antenatal booking: first official check-up in pregnancy
- Apgar: measure of newborn wellbeing
- **BMI: Body Mass Index** [as kg/m², <18.5, underweight; \geq 25, overweight; \geq 30, obese I; \geq 35, obese II; \geq 40, obese III]
- CGH: Caithness General Hospital
- CI: Confidence Interval
- CMU: Community Maternity Units
- CLU: Consultant Led Unit
- **CS:** Caesarean Section
- EGAMS: Expert Group on Acute Maternity Services
- FMU: Free-standing Midwifery Unit
- HDU: High Dependency Unit (adult)
- ICU: Intensive Care Unit (adult)
- Intrapartum: the period of time during labour and giving birth
- ISD: Information Services Division of the National Services Scotland, NHS Scotland
- LUSCS: Lower Uterine Segment Caesarean Section
- **MBRRACE:** Mothers and Babies: Reducing Risk through Reviews and Confidential Enquiries (UK-wide)
- Mortality and morbidity: to do with death or serious illness
- Multiparous: a woman who has borne more than one child
- Neonatal: relating to newborn children
- Neonatologist: doctor who specialises in the care of newborn children
- NICE: National Institute for Clinical Excellence
- NICU: Neonatal Intensive Care Unit
- NNH: 'Number needed to harm'
- Nulliparous: a woman who has never given birth
- Paediatrician: doctor who specialises in the care of children

Postpartum: the period beginning immediately after the birth of a child and extending for about six weeks

Primigravida: a woman who is pregnant for the first time (plural primigravidae)

PROM: Premature Rupture of Membranes

Quintile: one fifth of the population

RCM: Royal College of Midwives

RCOG: Royal College of Obstetricians and Gynaecologists

RR: Relative Risk

SCASMM: Scottish Confidential Review of Severe Maternal Morbidity

SCBU: Special Care Baby Unit

SCN: Special Care Neonatal Unit

10 Appendices

10.1 Caithness Neonatal Review Structure

Technical Review Team	Title
Dr Hugo Van Woerden (Chair)	Director of Public Health and Policy
Dr Cameron Stark	Consultant in Public Health
Dr Helen Bryers	Head of Midwifery
Dr Stephanie Govenden	Consultant Paediatrician
Dr Susan Vaughan	Epidemiologist
Liam Gaffney	Quality and Patient Safety Facilitator
Rachel Hill	Clinical Governance
Cathy Steer	Public Health
Angela Watt	Project Midwife

The members of the wider stakeholder group who were consulted on the project initiation document and used for expert advice are provided below.

Stakeholder Group	Title	
External Members		
Dr Brian Magowan	External Adviser, Consultant in Obstetrics & Gynaecology (NHS Borders)	
Dr Jane MacDonell	External Adviser, Consultant Paediatrician (NHS Borders)	
Dr Ian Laing	Clinical Lead, North of Scotland Neonatal Network	
Professor E. Draper	Professor of Perinatal and Paediatric Epidemiology	
Nicky Berry	External Adviser, Head of Midwifery (NHS Borders)	
Jenny McNicol	Head of Midwifery (NHS Grampian)	
Internal Members		
Dr Deborah Shanks	Head of Children's Services, Raigmore	
Mary Burnside	Lead Midwife N&W Operational Unit,& SOM	
Dr John MacLeod	CGH Clinical Lead	
Dr Lucy Caird	Clinical Lead in Obstetrics & Gynaecology, Raigmore Hospital	
Caron Cruickshank	Midwifery Manager & SOM, Raigmore	
Dr Philine van der Heide	Neonatal Clinical Lead	
Maryanne Gillies	Quality Improvement (patient safety)	
Sally Amor	Child Health Commissioner	
Alison MacLean	SCBU Charge Nurse	
Gill McVicar	Director of Operations, N& W Operational Unit	
Bob Silverwood	Area Manager, N&W Operational Unit	
Dr Paul Davidson	Clinical Director N&W Operational Unit	
Pauline Craw	CGH general Manager	
Laura Menzies	Acting Midwifery Team Leader	
Avril Andrews	Acting Midwifery Team Leader	
Dr Abdel-Aziz Essam	Consultant Obstetrician	
Dr Philip Boabang	Consultant Obstetrician	
Frances Arrowsmith	Sutherland Midwifery Team Leader & SOM	
Dr Jim Bingham	Link Consultant in Obstetrics & Gynaecology	
Isabel Seaton	Advanced Neonatal Nurse Practitioner	
Dr Rod Harvey	Medical Director	
Heidi May	Nursing Director	
Patricia Kelly	Training and Practice Development (Midwifery)	
Maimie Thompson	Head of Communications	
Mirian Morrison	Clinical Governance/Public Engagement	

10.2 Proforma for Assessment of Compliance with EGAMS Exit Criteria for Level 2a Unit and Supplementary NHS Highland Caithness Maternity Exit Criteria

Review Reference	
Number: CHI	
(maternal)	
Review Reference	
Number: CHI (baby)	
Reviewer (please	
initial):	
Initial booking	
place of birth:	

FORM SECTIONS

- 1. Maternal Medical & Obstetric Conditions at maternal booking (10-12 weeks)
- 2. Antenatal Conditions that changed the original booking pathway and place of birth
- 3. Intra-Partum exclusion criteria
- 4. Maternal postnatal problems
- 5. Neonatal Conditions (taken from EGAMS Level 1 and CMU exclusion criteria for birth in a Scottish CMU maternity unit)
- 6. Overall Care Summary

1. Maternal Medical & Obstetric Conditions at maternal booking (10-12 weeks)

Significant Respiratory Disease	Significant Neurological Disease	Cardiac Disorders
 Significant asthma i.e. requiring previous hospitalisation or parenteral steroid therapy Cystic fibrosis Congenital abnormality Emphysema (COPD) Certain congenital abnormalities 	 Neurological disorders, including ME, MS Epilepsy Spina bifida/hydrocephaly Paraplegia 	 34. Congenital heart disease – corrected or uncorrected 35. Acquired heart disease – ischaemic heart disease, cardiomyopathy
Haematological Disorders	Endocrine Disorders	Significant Gastro-intestinal Disorders
 Haematological disease – e.g. Thrombocytopenia, aplastic anaemia Coagulation abnormality – 	20. Significant endocrine disease21. Significant medical disease especially if	36. Fatty liver of pregnancy37. Hepatobilary disease38. Crohn's disease39. Ulcerative colitis

thrombophilia, disseminated intravascular coagulation9. (DIC) DVT or pulmonary embolus (any history)	unstable (thyroid, adrenal disease e.g. Addisons) 22. Diabetes (Type 1)	
Reproductive/Genital Tract	Musculo-Skeletal Disorders	Renal Disease
10. Cancer	23. Significant connective tissue disorder	40. Renal disease 41. Renal failure, impairment dialysis
Infection	Transplant Surgery	Significant Mental Illness
 Significant infection e.g. Group B haemolytic streptococcl Any blood borne virus (HIV, Hep B, Hep C) Sepsis 	24. Heart 25. Lung 26. Liver 27. Kidney	42. Diagnosed schizophrenia 43. Manic depressive psychosis
Drug or Alcohol Intake	Surgery & Anaesthesia	Genetic Disorders
 14. History of drug or alcohol abuse (There should be a review if the woman uses therapeutic medication) 	28. Any history of significant surgery or anaesthetic complication must be considered	44. Marfan's syndrome 45. Ehlers Danlos syndrome
Special Needs in Pregnancy	Neonatal History	Other
15. Will need to be independently considered e.g. Learning disability, Social exclusion, Refugee mother	 29. Any history of intrapartum asphyxia should be reviewed 30. Previous neonatal birth injury 31. Previous baby with haemorrhagic disease of the newborn 32. Risk of, or known, inherited disease 33. Previous iso-immunisation or ABO incompatibility 	46. Maternal BMI > 35 47. (Elective LSCS > 40)

1.1 Were any conditions itemised in the list above present?

Yes [] No [] If no, please go to 1.3

- If Yes, please circle the number relating to the relevant condition(s) in the list above
- 1.2 If a condition named above was present, was the woman placed on the red pathway?

Yes	[]	No	[]	Not Applicable	[]	(Please Tick as appropriate)
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1.3 Please record any comments about care here:

Summary after maternal booking:

<u>According</u> to the information in the case notes:

1.4	At this stage, was the care pathway red or green?*	Red]]	Green	[]
1.5	Please state the advised place of birth as per case notes?	Raigmore	• []	Caithness	[]

*It may not be stated as "red" or "green" in the notes but reviewer should be able to deduce the actual pathway from the notes

Given the information in the case notes, in your judgement:

1.6	Was the care appropriate at this stage?	Yes]	[] No	[
-----	---	----------	--------	---

Maternal	Fetal/Combined	Fetal/Baby
48. Maternal choice	59. Maternal infection (HIV,	71. Post-maturity>40/52+10
49. New medical disease not previously identified	Hepatitis carrier, Hep B, Hep C, Group B streptococcal)	days 72. Suspected or proven fetal
50. Significant antepartum haemorrhage	60. Polyhydramnios	73. Intrauterine death
51. Cholestasis (including	61. Oligohydramnios	74. Significant Child Protection
fatty liver of pregnancy	62. Multiple pregnancy	Issues
and HELPP) 52. Severe pregnancy	63. Preterm labour <37 completed weeks	75. Suspected IUGR (EFW < 2.5kgs)
induced hypertension	64. Membrane rupture <37	- 5-7
anaesthetic risk	65 Malprosontation > 37	
54. Women at high risk of obstetric interventions	completed weeks (including breech)	
which may require assistance of interventional radiology (eq placenta accreta) or	66. Active viral infections such as chickenpox, rubella, measles, parvo-virus	
severe PPH>4000mls	67. Current therapeutic drug	
55. Raised AFP with abnormal growth scan at	use (Benzodiazepines, any psychotrophic drugs)	
34-36 weeks	68. Large for dates by U/S	
56. Placental abruption	(over 90" centile)	
57. Placenta praevia	69. ABO, rhesus iso- immunisation	
58. Newly diagnosed cancer	70. 'At risk' foetus	

2. Antenatal Conditions that changed the original booking pathway and place of birth

2.1 Were any conditions itemised in the list above present, and identified after booking?

Yes [] No [] If no, please go to 2.3

• If Yes, please circle the number relating to the relevant condition(s) in the list above

2.2 If a condition named above was present, was the woman placed on the red pathway?

Yes [] No [] Not Applicable [] (Please Tick as appropriate)

2.3 Please record any comments about care here:

Summary of antenatal conditions identified after booking:

<u>According</u> to the information in the case notes:

2.4	At this stage, was the care pathway red or green?*	Red	[]	Green	[]
2.5	Please state the advised place of birth as per case notes?	Raigmore	[]	Caithness	[]

*It may not be stated as "red" or "green" in the notes but reviewer should be able to deduce the actual pathway from the notes

Given the information in the case notes, in your judgement:

2.6	Was the care appropriate at this stage?	Yes]	[] No	[
-----	---	----------	--------	---

3. Intra-Partum exclusion criteria

Maternal	Maternal/Combined
76. Postpartum haemorrhage (>500 mls)	82. Intrapartum haemorrhage
77. 3 rd or 4 th degree perineal tear	83. Newly diagnosed medical disease or
78. Mother gives cause for concern	morbidity
79. Retained placenta	84. Maternal pyrexia>38 ^o C on two
80. Placenta acreta	
81. Obstetric condition that may result in ITU (e.g., DIC following placental abruption)	

3.1 Were any conditions itemised in the list above present, and identified during labour excluding elective caesarean sections?

Yes [] No [] If no, please go to 3.3

- If Yes, please circle the number relating to the relevant condition(s) in the list above
- 3.2 If a condition named above was present, what action was taken?

3.3 Please record any comments about care here:

Summary of intra-partum exclusion criteria:

<u>According</u> to the information in the case notes:

3.4	At this stage, was the care pathway red or green?*	Red	[]	Green	[]
3.5	Please state the advised place of birth as per case notes?	Raigmore	[]	Caithness	[]

*It may not be stated as "red" or "green" in the notes but reviewer should be able to deduce the actual pathway from the notes

Given the information in the case notes, in your judgement:

3.6 Was the care appropriate at this stage?	Yes]	[] No	[
---	----------	---------------	---

4. Maternal postnatal problems

4.1 Postnat al	Criteria	Present (Y/N)	Transf er (Y/N)	Comments Please indicate whether occurrence in hospital or after initial discharge home
a)	PPH > 1500 (Caithness Exit 2012)			
b)	Persistent pyrexia > 38C (Caithness Exit 2012)			
c)	Sepsis (Caithness Exit 2012)			
d)	Other significant problems (EGAMS)			

4.2 Other Comments on care:

Summary of maternal postnatal problems:

<u>According</u> to the information in the case notes:

4.3	At this stage, was the care pathway red or	Red	[]	Green	[]	7
	green?*	nou	L 3	Oreen	_ L _ J	

*It may not be stated as "red" or "green" in the notes but reviewer should be able to deduce the actual pathway from the notes

Given the information in the case notes, in your judgement:

4.4	Was the care appropriate at this stage?	Yes]	[] No	[
-----	---	----------	--------	---

5. Neonatal Conditions (taken from EGAMS Level 1 and CMU exclusion criteria for birth in a Scottish CMU maternity unit)

Neo	natal
85. Birth weight <2500g	92. Feeding difficulties persisting at 36 hours
86. Large Baby >4000g	of age
87. Neonatal seizures	93. Failure to pass urine in first 24 hours
88. Persisting hypothermia	94. Suspected SEPSIS (Caithness Criteria)
89. Baby gives cause for concern	95. Jaundice in first 24 hours/positive Coombes test
90. Apgar score 7 or less at 5 minutes of age and/or < 9 after 10 min	96. Persisting hypoglycaemia
91. Respiratory difficulties after resuscitation (respiratory rate >60/min or requiring supplementary oxygen to maintain saturation >92%)	97. Failure to pass meconium in first 36 hours

5.1 Were any conditions itemised in the list above present?

Yes [] No [] If no, please go to 4.3

- If Yes, please circle the number relating to the relevant condition(s) in the list above
- 5.2 If a condition named above was present, what action was taken?

Summary of neonatal conditions:

According to the information in the case notes:

5.4	Was the care pathway red or green (for the baby)?*	Red	[] Green	[]
5.5	Was a neonatal transfer required?	Yes]	[] No	[

*It may not be stated as "red" or "green" in the notes but reviewer should be able to deduce the actual pathway from the notes

Given the information in the case notes, in your judgement:

5.6	Was the care appropriate at this stage?	Yes]	[] No	[
-----	---	----------	--------	---

6. Overall Care Summary

Summary of overall care for the mother:

According to the information in the case notes:

6.1	Was the overall care pathway red or green?*	Red []	Green	[]
6.2	Please state the overall advised place of birth		1	Ositheras	Г	1
0.2	as per case notes?	Raigmore	1	Caltnness	L	1

*It may not be stated as "red" or "green" in the notes but reviewer should be able to deduce the actual pathway from the notes

Given the information in the case notes, in your judgement:

6.3	Was the overall care appropriate at this stage?	Yes]	[] No	[
-----	---	----------	---------------	---

Summary of overall care for the baby:

According to the information in the case notes:

6.4	Was the overall care pathway red or green?*	Red	Green	[]
65	Please state the overall advised place of birth		Osithassa	г	1
0.5	as per case notes?	Raigmore	Caltnness	L	J

*It may not be stated as "red" or "green" in the notes but reviewer should be able to deduce the actual pathway from the notes

Given the information in the case notes, in your judgement:

6.6	Was the overall care appropriate at this stage?	Yes]	[] No	[
-----	---	----------	--------	---

6.7 Other Comments on overall care:

10.3 Caithness Maternity Review – review tool

For events occurring in the period Sept-2010 to Aug-2015 incl.

As part of Objective 2, the review of selected cases of neonatal transfers (all \geq 37wks & \geq 2.5kg & transfer < 1 month after birth), all neonates with Apgar score \leq 7 (at 5 minutes) and a representative sample of maternal transfers within 10 days of birth were undertaken. The technical review team agreed a pragmatic approach to this involving application of a screening tool by local reviewers to identify the presence of risk factors known to be associated with poorer outcomes. For any such cases found, the case notes were then further reviewed by a wider external team to decide on cases where the management was sub-optimal.

For events occurring in the period Sept-2010 to Aug-2015 incl.

PLEASE COMPLETE SECTIONS 1 & 4 WITH EITHER SECTION 2 OR 3 DEPENDING ON TYPE OF CASE

① Case Details

CHI (maternal):		
CHI (baby):		
Type of case:	Apgar ≤ 7 @ 5 mins	 complete sections ${\mathscr O}$ and ${\mathscr O}$
	Neonatal transfer	 complete sections ${\mathscr O}$ and ${\mathscr A}$
	Maternal transfer	 complete sections ${\mathscr S}$ and ${\mathscr A}$

② Apgar ≤ 7 @ 5 mins (n=15) or neonatal transfers (n=33)

Known at 4 hours or later after birth for all births

- (i)Cord $pH \le 7.1$ (ii)Low blood sugar < 2.6 mmoles/I @ 2 readings</td>(iii)Temp. < 36.5° C or $\ge 38.0^{\circ}$ C(iv)Oxygen requirement or CPAP(v)Signs of sepsis
- (vi) Respiratory distress

Was there a plan of care?



P.T.O

$\overline{\mathbf{A}}$		4	
3	Maternal	transfers	(n=38)

Known at intrapartum or postpartum

 (i) (ii) (iii) (iv) (v) (v) (vi) (vii) (viii) (ix) 	Infection Abnorm Intrapart Pre-ecla Eclamps Signs of Pre-term SRM <3 SRM >3	of uterin al CTG um / post mpsia sia sepsis in a labour (- 7w 7w+24h	e membrar partum hae mother an <37w)	e (chorioai emorrhage d unborn b	mnionitis) aby		
			Was there	a plan of ca	are?		
④ Scree	ning F	lesult					
This case shou	ld be sent	for furthe	r review		Yes [ב	No
Any comment?							
Case screened I	by:						
Date:		/.	/				

10.4a Review panel proforma for Objectives 1

Case Number:

Priority number:

PROFORMA: Review of audited cases against the EGAMS Exit criteria identified as having overall inappropriate care for mother and/or baby (i.e. "no" in sections 6.3 &/or 6.6 of the audit tool)

CHI (maternal)	Original Reviewer (s)	
CHI (baby)	Initial booking	Place of Birth

A. Problem/Issue identified

Complete the following based on the agreement of the review team (AANP/Paediatrician/Midwife/non-NHS H Obstetrician)

B. What should have been done to minimise the risk to Mother and/or Baby?



D. If CGH had been a midwife-led unit, would the problem have arisen? Indicate the degree to which it could have arisen by marking the relevant box:



PT

10.4b Review panel proforma for Objectives 2 (excluding perinatal deaths)

Case Number

Priority number:

PROFORMA: Review of cases identified with issues/concerns according to the screening tool of Neonatal transfers; Maternal transfers and neonates with low Apgar scores (≤7)

CHI Maternal		Apgar ≤ 7 @ 5m	
CHI Baby	Type of	Neonatal transfer	
	04001	Maternal transfer	

A. Problem/Issue identified

Complete the following based on the agreement of the review team (AANP/Paediatrician/Midwife/non-NHS H Obstetrician)

B. What should have been done to minimise the risk to Mother and/or baby?

PTO C. What needs to be done to avoid this occurring in the future? PTO

D. If CGH had been a midwife-led unit, would the problem have arisen? Indicate the degree to which it could have arisen by marking the relevant box:



11 Annex 1: First External Report

CAITHNESS AND RAIGMORE MATERNITY and NEONATAL SERVICES EXTERNAL REVIEW OF TEAM WORKING AND ORGANISATIONAL CULTURE

Aim of the inspection

The aim of the external inspection was to examine obstetrics and neonatal services at Caithness General Hospital (CGH) to ensure that the safest possible care for mothers and newborns is provided. The key purpose of this external inspection was to satisfy both the local population and the NHS Highland Board that systems and processes in CGH can ensure the safe care of newborns given the unique challenges faced by the hospital and its system of obstetric care without co-located paediatric expertise.

The visiting team spent a day in CGH in discussion with the Lead Midwife, the Senior Charge Midwife, members of the Midwifery Team, the Managerial Lead, the Clinical Lead, an Anaesthetist and a Sister from Theatre. The second day was spent in Raigmore in discussion with the Midwifery Lead, Advanced Neonatal Nurse Practitioners (ANNPs), Senior Charge Midwives from the antenatal labour ward and neonatal unit, Paediatricians, Obstetricians and the Director of Public Health for NHS Highland.

Background

CGH serves a largely rural and relatively socially deprived area of the Highland Region and is approximately 2-2.5 hours by road from Inverness. It has a consultant-led obstetric unit but no paediatric or neonatal staff presence. Recruitment to senior medical posts has been, and continues to be, problematic given the unit's isolation, difficulty in keeping up skills because of small patient numbers, and the lack of opportunity for regular training. Whereas in the past there has been the availability of a GP with some surgical or paediatric skills to contribute to the hospital service, this is no longer the case and is unlikely to be replicated in the future. Similarly, anaesthetic posts are frequently covered by locums who cannot be expected to have the skills necessary to manage acutely ill newborn babies.

There are approximately 230 maternities in Caithness annually, of which around 140-160 usually deliver in CGH. The remainder travel to Raigmore Hospital, Inverness. Since a Significant Adverse Event Review in 2015, special measures have been in place such that certain groups, in particular primigravidae and those wishing an elective cesarean section, are being delivered in Raigmore. This means that the deliveries in CGH are reduced, and estimated to be between 30-70/year.

Findings

Caithness (Wick)

- In our discussions with medical and midwifery staff, it was recognised that CGH is a relatively small hospital (approx 60 beds) with major recruitment challenges to medical, nursing, and midwifery posts. The midwifery funded complement is over 13 and there are currently fewer than 10 whole time equivalents in post. This has implications for staffing the service, much of which has been achieved by the good will of the midwives. It also provides challenges in releasing staff for training. The road journey to Raigmore takes approximately 2 hours in good driving conditions, though transfer to and from the ambulance will add to this time overall.
- There has been a slow reduction in the birth rate within the catchment area of CGH.
- The midwifery staff appeared motivated and enthusiastic, although understandably frustrated by the uncertainties and the limitations of the interim measures. There was a strong sense of 'team' within this group. Additionally, most of the midwives interviewed at SGH had a preference to repatriate the primigravidae and the elective sections.
- Although there is a consultant-led maternity service there is no neonatal paediatric cover. Neonatal care is provided by the midwives, supported by local medical staff and with advice from other staff at Raigmore via telephone or videolink. The midwives are willing to continue in this role providing there is ongoing support from the other staff members but there remain issues around how skills can be developed and maintained given the requirements for service provision. It was the Review Group's impression, however, that the CGH medical staff, (and all of the Raigmore staff see below), were not enthusiastic about providing this support or their ability to do so on a consistent and future basis, and expressed a preference that the service at CGH become a Community Midwifery Unit (CMU).
- There were concerns over midwifery deskilling, especially with the current position of delivering approximately 1 baby per week.
- There were also concerns over the reality of the time taken for neonatal transport, with delays of 10-12 hours being not uncommon depending on other calls to the retrieval team.
- The Consultant Obstetrician interviewed had a preference to provide 9-5 cover, but was less clear about how the service could be provided outwith this time.
- The Consultant Anaesthetist interviewed expressed concerns about whether (m)any anaesthetists, especially locums, would consistently have the skills to support neonatal care.
- Ultrasound scans are carried out by one radiographer only.
- There is apparently strong public support for keeping a consultant-led maternity service, but it was unclear how truly informed this view was around the absence of neonatal cover and the risks to a baby who becomes significantly unwell.
- There are good teleconference facilities, and both the daily phone calls and weekly teleconferences have been helpful.
- The ANNP training visits have also been helpful, especially around the Neonatal Resuscitation Program (NRP).
- Communication with the ANNPs in Raigmore was highly valued, but communications
 with specialist trainees were felt to be of variable quality. Communication with the
 Paediatric Consultants was also felt to be very helpful, but there was limited support for
 continuing this from the Consultant Paediatricians at Raigmore beyond the current
 interim measures, especially over less acute problems, because of the multiple
 demands on their time (as below).

Raigmore (Inverness)

- There was a strong impression from all staff interviewed that CGH should become a CMU; none favoured returning to the previous arrangement. One consultant member of the obstetric staff had a preference for no service in CGH at all.
- The Consultant Paediatricians had concerns around neonatal safety in a consultant obstetrician-led unit with no neonatal support. This included the question of who had responsibility for the baby's care at CGH and who carried the ultimate responsibility for babies when the Raigmore staff were only offering remote clinical advice. Their advice, they felt, could only be based on the information they were given and, while this was usually very good, it was sometimes hard to be absolutely certain about specific details. They expressed the view that they were often busy in different areas while on call, and were not keen to continue being the first point of contact for clinical scenarios that would usually be locally dealt with by specialist trainees. It was acknowledged that junior paediatric staff needed to be given a better appreciation of the nature and geographical remoteness of the CGH unit so that appropriate advice could be given and that a consultant paediatrician at Raigmore should always be available to discuss a problem if CGH or the Raigmore junior doctor considered this necessary.
- Midwives felt that the CMU in Fort William, which has a similar catchment area to Caithness although slightly closer in terms of transport time, worked well. The CMU in

Broadford apparently also works well and has a similar transfer time to Inverness as CGH.

Summary

Due to its geographical isolation (although this is not greatly different to other comparable units for which Highland Health Board has responsibility, such as Fort William and, particularly, Broadford), CGH presents particular difficulties in the provision of joined-up care for mothers and babies if the latter become significantly unwell. The provision of consultant-led obstetric care in the absence of comparable paediatric / neonatal care is anomalous compared to services provided to the rest of the population served by Highland Health Board. Historically expertise has been provided on an ad hoc basis but, with increasing medical specialisation, that is now impossible and this situation is extremely unlikely to change.

In socio-economic terms the population served by CGH is relatively deprived and itself geographically widely spread and remote from hospital-based services.

There appears to be no realistic prospect of providing neonatal cover in CGH using neonatal consultants, paediatric consultants, middle grade medical staff or ANNPs. Recruitment to these types of posts has apparently not been possible despite repeated attempts to do so, and there is no prospect of training up ANNPs locally. This situation is extremely unlikely to change for the better in the future.

Current neonatal care in CGH is provided by the midwives, who remain willing to take on this role. They have traditionally been supported locally by anaesthetic staff within the hospital, but anaesthetists within this post often lack paediatric experience and sometimes have no neonatal or even paediatric experience at all. Regionally, support within the working day has been with ANNPs in Raigmore, but recruitment to train new staff in these posts is also low. Support out of hours has been with the paediatric specialist trainees or GP ST trainees, who often don't appreciate the geographical challenges, and with paediatric consultants, who are already busy and are uncomfortable about clinical decision making at a distance. It is acknowledged that there has been improved communication between the midwives in CGH and the midwives an Due to its geographical isolation (although this is not greatly different to other comparable units for which Highland Health Board has responsibility, such as Fort William and, particularly, Broadford), CGH presents particular difficulties in the provision of joined-up care for mothers and babies if the latter become significantly unwell. The provision of consultant-led obstetric care in the absence of comparable paediatric / neonatal care is anomalous compared to services provided to the rest of the population served by Highland Health Board. Historically expertise has been provided on an ad hoc basis but, with increasing

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Conclusion

No possible model of care is risk-free or can guarantee the safety of mothers and babies delivered at CGH in all circumstances. The optimal model will minimize disruption to the majority of mothers and babies in whom all will be normal medically but also minimise the risk of harm when medical problems arise. It must also be sustainable in terms of likely resources and skill availability.

Given the apparently insuperable problem of ensuring the local availability of safe neonatal cover, it was the unanimous clinical view of this Review Team that the maternity service in Caithness should be reconfigured as a CMU.

It is recognised that such a change to the configuration of service provision will raise further issues. These include the necessity of providing increased resources to Raigmore to deal with the increased numbers of mothers and babies who will be referred there. There is also the potential risk that those continuing to provide the reduced services in CGH will become more deskilled. Nevertheless the Review team believes that the balance of risk is firmly in favour of the solution that we propose. The Review team recognise that the local community in Wick and Caithness may be resistant to this proposal, and in particular the loss of a consultant obstetrician presence, but it was our impression from the professional views expressed that there may have been (and continue to be) a lack of appreciation of the potential risks to babies associated with the pattern of deliveries undertaken at CGH without the presence of skilled neonatal paediatric staff should something go wrong or a baby become unwell.

The consequences of any other solution would need to be explicitly explained to, and understood by, the local community. Any such decision would need to rest with whichever political group took such a decision, and would need to explicitly exonerate the clinical staff in both Caithness and Raigmore from the consequences. If such risks are ones that potential parents could be willing to accept, the lack of neonatal support and its potential consequences would need to be explicitly stated, and care taken to ensure that such views are truly informed and are also representative of maternity care users.

Specific questions that may arise from this opinion

1. Would it be appropriate to have a consultant led unit, but using CMU selection criteria? It was the view of the Review Group that this would continue to blur the boundaries between acceptable practice in a CMU versus a consultant-led unit: there could be the temptation to deal with more complex obstetric problems than would be delivered at comparable units (e.g. Fort William or Broadford), or that mothers might choose to come to Caithness knowing that there was an obstetric consultant available, while not fully appreciating that there was no neonatal support and the potential consequences of this.

2. Should elective caesarean sections be repatriated from Raigmore to Caithness? This group is considered to be a low risk group providing delivery is undertaken after 39+0 weeks, but it was recognized that maternal complications can occur, not all of which could be dealt with in Caithness. The chance of neonatal problems is likely to be very low, and probably comparable to vaginal deliveries in low risk women. There could be a tendency, however, to opt for a elective caesarean section if vaginal birth after caesarean was locally unavailable.

3. Should primigravidae deliver in the CMU? This group was felt to be too high a risk for intrapartum transfer (estimated at around 40%), and that the chance of neonatal problems was also likely to be increased over the lower risk parous group.

Suggestions to facilitate the transition

- A common theme from both CGH and Raigmore was the lack of facilities for mothers waiting to go into labour in Raigmore. This could be considerably improved by a new comfortable, family-centered, facility in Raigmore.
- Transport delays could be improved with the purchase of a transport pod to allow babies to be transferred to Raigmore by this method, although this would require defined criteria for transport and a sufficiently trained staff member at CGH to accompany the baby.
- Some increased resource might be required in Raigmore to support the increased numbers of deliveries.
- Consideration will need to be given around the delivery of gynaecology services at CGH and the implications for service delivery at Raigmore.

Dr Brian Magowan, Consultant Obstetrician, NHS Borders

Dr Jane Macdonell, Consultant Paediatrician, NHS Borders

Mrs Nicky Berry, Head of Midwifery, Assistant Nurse Director, NHS Borders

Prof. Chris Kelnar, Consultant Paediatrician and Paediatric Endocrinologist at the Royal Hospital for Sick Children, Edinburgh

There are no declared conflicts of interest.

12 Annex 2 – Second External Report





The Infant Mortality & Morbidity Studies

External Clinical Governance Review of Five Perinatal Deaths from Caithness Hospital

Professor Elizabeth S Draper

Professor David J Field

October 2016

Governance review of five consecutive perinatal deaths whose care was organised from Caithness Hospital, Scotland

Summary

This document reports the findings of an independent enquiry into five perinatal deaths identified to have occurred in relation to care provided by Caithness hospital from August 2010 to August 2015. The relevant records for each case were extracted by staff from the Hospital and transferred to the TIMMS (The Infant Mortality and Morbidity Studies) office at the University of Leicester. Additional material was requested from the relevant organisations where important aspects of the case records appeared to be missing. Cases were then reviewed independently by an obstetrician, a neonatologist, a midwife and a neonatal nurse who were all from different Trusts, and in addition by Prof Field (also a neonatologist). A consensus meeting was then convened by Prof Draper (perinatal epidemiologist) and aspects of good and poor care documented using a standardised system of documentation developed by TIMMS.

Background

In the early months of 2016 the TIMMS perinatal team were approached by NHS Highland following the unexpected death of a mature baby from the Caithness area in 2015. Given the low volume of the Caithness maternity unit an independent review of the circumstances around this baby's death and other perinatal deaths that had occurred in the previous five years (August 2010 to August 2015) was requested to try and identify avoidable factors that might have contributed to these deaths and in addition factors which might be of relevance more generally to the delivery of perinatal care within the hospital. A total of five cases (two stillborn infants and three neonatal deaths) were sent to the external panel for review. The specific terms of reference were:

1. To provide an overview of the care of each stillbirth / neonatal death along all aspects of the care pathway – including use of the transport team – with final assessment of the overall quality of care for each case;

2. To provide an assessment of clinical decision making processes for each case identified for review;

3. To review medical, nursing and midwifery profiles for each case identified for review;

4. To assess the availability and access to clinical support for each case identified for review.

Methods

The review took the form of a multidisciplinary review involving an obstetrician, a neonatal paediatrician, a neonatal nurse and a midwife. Potential panel members were approached on the basis that they had significant clinical experience at a senior level, experience of the review methodology and had no conflict of interest. Key members of the review also had experience of the Care Quality Commission hospital review process.

Once the records were received copies were taken and sent to each member of the review team including Prof D Field (neonatologist) and Prof E Draper (perinatal epidemiologist) who were responsible for overseeing the review.

Each team member was asked to make a narrative description of the cases and to grade all notable aspects of the care received using the standard template employed by TIMMS when carrying out such reviews (see figure 1) following the standard methodology (1,2). The review team were asked to consider all phases of the care in each case commencing with the antenatal care given to the mother and continuing through the labour and delivery and concluding with the care given to the baby. It can be seen that the form asks not only the nature of any particularly good or poor care identified but also whether it was likely to have affected the outcome in the case and finally who was responsible (e.g. consultant obstetrician, locum obstetric registrar, registered midwife etc.). When completing the templates panel members were asked to record only notable factors and therefore the comments included in the summary forms about each case below focus only on certain aspects of the care pathway.

At the panel meeting each case was firstly presented to the group by the allocated lead panel member. The chair (Prof Draper) then led the review of each case along each point of the care pathway, establishing a consensus opinion for each identified issue and an overall summary score for the quality of care provision for each case (Box 1).

BOX 1 – Grading for sub-optimal care

Sub optimal care grade	Definition
0	No sub-optimal care
1	Sub-optimal care, but different management would have made no difference to the outcome.
2	Sub-optimal care in which different management might have made a difference to the outcome (i.e. an avoidable factor of uncertain influence on outcome).
3	Sub-optimal care in which different management would reasonably be expected to have made a difference to the outcome (i.e. an avoidable factor that contributed to a poor outcome).

Review findings

Case 1- Neonatal death

This case related to the death of a liveborn baby. The key omission in this case was a failure to recognise and act upon the signs of early infection. The midwifery staff did seek specialist help but this was significantly delayed. The potential for the child to be affected by infection was not recognised by the senior paediatric / neonatal trainees involved.

Case 1 overall Grade: 3 Sub-optimal care in which different management would reasonably be expected to have made a difference to the outcome (i.e. an avoidable factor that contributed to a poor outcome).

Case 2 - Stillbirth

This case relates to a woman who suffered a stillbirth at 25 weeks of gestation. The panel felt that the delay in providing a second opinion (arranged for the following day) to confirm the death of the foetus represented a poor standard of care. Supervision and documentation during labour was also felt to be suboptimal especially given that this mother had had a previous caesarean section.

Case 2 overall Grade: 2 Sub-optimal care in which different management might have made a difference to the outcome (i.e. an avoidable factor of uncertain influence on outcome).

Case 3 – Stillbirth

This case relates to a young women who suffered a stillbirth at term +10 days. This was a high risk pregnancy with complex medical and obstetric problems which increased after 33 weeks due to possible rupture of membranes. There were particular problems with access to accommodation in Inverness (the Inverness unit, Raigmore, responsible for more specialist input) which meant that she returned to Caithness with no plan for induction of labour. Overall care was poorly organised between the two services with communications issues, particularly between the patient and Raigmore, seeming to be prominent.

Case 3 overall Grade: 3 Sub-optimal care in which different management would reasonably be expected to have made a difference to the outcome (i.e. an avoidable factor that contributed to a poor outcome).

Case 4 – Neonatal death

This case relates to a neonatal death of a term infant. The mother presented in labour but growth restriction does not seem to have been considered despite the baby having been noted antenatally to have been on the 6th centile of a customised growth chart.

Case 4 overall Grade: 2 Sub-optimal care in which different management might have made a difference to the outcome (i.e. an avoidable factor of uncertain influence on outcome).

Case 5 – Neonatal death

This case relates to a neonatal death. There appears to have been no recognition of the risk of preterm labour and this resulted in a birth at home.

Case 5 overall Grade: 2 Sub-optimal care in which different management might have made a difference to the outcome (i.e. an avoidable factor of uncertain influence on outcome).

Summary of Findings

General Themes

The cases were reviewed without any background detailed knowledge of events / issues at the hospital during the time that the births under review took place (e.g. staffing structure, levels of activity, use of agency staff, vacancy rates etc.). However during the review of records certain issues arose which appeared relevant. These included:

1. **Activity levels / isolated setting**. It was clear that the total number of births in Caithness was very low and that resident obstetric cover is only available for very limited periods. Out of

hours consultant obstetric cover is available but the doctors have to attend from home and can be up to 30 minutes away. There is no in-house paediatric / neonatal cover. This is available in Inverness and can also be accessed by teleconference link. Travelling time from Caithness to Inverness clearly varies with the road conditions but the average time to cover the nearly 100 miles is reported as around three hours. It seems that accommodation for antenatal mothers needing regular review in Inverness, but not admission, is available but is free only for a limited number of days.

2. **Support to vulnerable mothers** There appears to have been very good access to midwifery support and consultant input for all of the cases reviewed. However there were psycho social issues present in three of the cases and the provision of wider support, particularly when a pregnancy complication led to the need for review in Inverness, was clearly difficult to deliver.

3. **Availability of specialist obstetric services** Although patients in Caithness clearly have access to a consultant led obstetric service and staff trained in neonatal resuscitation the low number of deliveries will inevitably limit the type of interventions that can be provided and the skill set that can be maintained. The panel were unable to ascertain how the service was portrayed to pregnant women considering where to book for their pregnancy. This is a particular issue where women are not entirely low risk.

Conclusion

The limitations of what can provided for babies born in this setting are exemplified by the events surrounding the index case that led to this review. The index child died of an infection which was certainly capable of treatment and, on the balance of probability, earlier treatment of infection would have led to the baby's survival without long term impairment. However for this to have happened would have required a closer and more cautious approach to care of the potentially sick newborn as well as channels of communication that involved senior staff at the earliest stages of any abnormality noted in the course of the low risk babies delivered in the Caithness unit. Inevitably such an approach will lead to more regular involvement of the neonatal team in Inverness (such as a daily telephone contact by the consultant about the previous day's births and babies still in the hospital) and some extra transfers. However given that very serious conditions, such as septicaemia, can present with very subtle signs the involvement of specialist staff with the appropriate skills and training seems to be a more feasible means of avoiding this type of incident as opposed to "training" staff in Caithness. This approach could be supplemented by the use of the NEWS (Neonatal Early Warning System) approach to monitoring.

In relation to obstetric and midwifery care the service at Caithness appears (in relation to these cases) to operate to a satisfactory standard. However the geography and the nature of the staff available set limits on what can be provided without transfer. It is important that these limitations are made clear to women who book at this unit.

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Publication produced and published by NHS Highland Public Health, November 2016

ISBN: 978-1-901942-17-0

