

THE MORECAMBE BAY INVESTIGATION

Chaired by Dr Bill Kirkup CBE

The Morecambe Bay Investigation
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RESTRICTED MARKING

Dr David Cromwell
Director, Clinical Effectiveness Unit
The Royal College of Surgeons of England
35-43 Lincoln's Inn Field
London WC2A 3PE

03 December 2013

Dear Dr Cromwell

ACCESS TO HOSPITAL EPISODE STATISTICS DATA

As you may be aware, on 12 September 2013 the Secretary of State for Health announced an independent investigation into the maternity and neonatal services provided by the University Hospitals of Morecambe Bay NHS Foundation Trust.

Between January 2004 and June 2013 there were a series of deaths of mothers and newborn babies in the maternity and neonatal services unit at Furness General Hospital. Several reviews took place during this period. However, these reviews have not given those affected confidence that all of the facts have been heard and all of the underlying issues have been resolved.

The Investigation's analyst, Hannah Knight, informs me that the Clinical Effectiveness Unit (CEU) at The Royal College of Surgeons of England holds a full copy of the Hospital Episode Statistics (HES) database, and that the analysis of the maternity data contained therein may help to address certain questions about the management, delivery and outcomes of care provided by the Trust that are relevant and pertinent to the Investigation's terms of reference (enclosed).

I also understand that Hannah Knight is an honorary Research Associate at the CEU, and that she already has access to HES data via a secure remote server. The purpose of this letter is therefore to formally request permission for Hannah to use the CEU's copy of the HES database for the purposes of the Morecambe Bay Investigation.

I would be grateful if you could advise me, in writing, if the Royal College of Surgeons can agree to this request, and if so, whether the College has a standard approach to formalising such requests by means of a Data Sharing Agreement or Memorandum of Understanding.

Should your response be positive and the Investigation can access the data there will, I recognise, need to be further discussions regarding how any data is ultimately reported by the Investigation.

If you have any queries please do not hesitate to contact me.

Yours sincerely

Oonagh McIntosh
Secretary to the Investigation

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Dr David Cromwell
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14 January 2014

Dear Dr Cromwell

ANALYSIS OF HOSPITAL EPISODE STATISTICS DATA

Further to our recent telephone conversation and your subsequent discussion with Hannah Knight, I am writing to confirm that the Morecambe Bay Investigation wishes to commission the Clinical Effectiveness Unit (CEU) at The Royal College of Surgeons of England to carry out an analysis of Hospital Episode Statistics (HES) data.

The purpose of the analysis will be to determine whether the University Hospitals of Morecambe Bay NHS Foundation Trust was an outlier for particular maternal and neonatal outcomes during the period 1 January 2004 to 1 June 2013, for example:

- Maternal and perinatal death
- Severe adverse maternal outcomes
- Severe adverse neonatal outcomes
- Long-term complications associated with birth trauma

I would be grateful if you could provide a detailed list of the analyses that you plan to conduct, the methods that will be employed, and a time scale for the delivery of this work. Please also include a breakdown of the estimated costs.

The work should not commence until the planned analyses have been agreed by the Investigation's Chairman and I have had the opportunity to consider the estimated costs.

If you have any queries please do not hesitate to contact me.

Yours sincerely,

OONAGH MCINTOSH
SECRETARY TO THE INVESTIGATION

Independent investigation into the management, delivery and outcomes of care provided by the Maternity and Neonatal services of University Hospitals of Morecambe Bay Trust from January 2004 – June 2013

Variation to Contract

CONTRACT TITLE:	Gorkana Press Cuttings and Media Monitoring Service				
FOR THE PROVISION OF:	Provision of Electronic and Hard Copy Press Cuttings Service – incorporating Data handling and Protective Marking				
CONTRACT REF:	13941	VARIATION NO:		DATE:	5 th February 2014

TERM: 1st December 2013 to 30th November 2014 (12 months)

COST: Estimated as up to 2400 clips @ 89p per clip = £2136.00 + vat

BETWEEN:

The Secretary of State for Health (hereinafter called the Department) and Gorkana Ltd, (hereinafter called the Contractor) having his main or registered office at 28-42 Banner Street, London, EC1Y 8QE:

The Contract is varied as follows:

The Department wishes to extend access to the contract to incorporate requirements that support The Morecambe Bay Investigation.

Search medium and criteria will be specified in agreement with Tom Bacon, Deputy Secretary, Morecambe Bay Investigation.

Investigation search terms:

- Morecambe Bay Investigation - *(the title the Investigation is known as)*
- Morecambe Bay Maternity and Neonatal Services Investigation - *(the official title of the Investigation)*
- Dr Bill Kirkup - *(the Investigation's Chairman)*
- Furness General Hospital - *(the hospital predominantly under Investigation)*
- University Hospitals of Morecambe Bay Trust - *(the name of trust under the Investigation)*

Local media to be monitored in additional to the standard regional and national:

- News and Star
- North West Evening Mail
- The Cumberland News
- The Times and Star
- Lancaster Guardian
- Lancashire Telegraph
- Lancashire Evening Post

Broadcast media to be monitored:

- BBC Lancashire Radio
- BBC Cumbria Radio
- The Bay Radio

The variation covers access for 6 users drawn down from the Department's NLA Licence.

Invoicing will be arranged under separate PO specific to the Morecambe Bay Investigation. Investigation invoices should be sent separately from those for the attention of the Department's Press Office.

Words and expressions in this Variation shall have the meanings given to them in the Contract.

The Contract, including any previous Variations, shall remain effective and unaltered except as amended by this Variation.

SIGNED:

FOR: THE AUTHORITY

By

Full name

GRADE / PAY BAND

DATE

FOR THE CONTRACTOR

BY

FULL NAME: ALEX HUNTER

TITLE: ACCOUNT DIRECTOR

DATE: 13.02.14

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Dr David Cromwell
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London WC2A 3PE

24 February 2014

Dear Dr Cromwell

ANALYSIS OF HOSPITAL EPISODE STATISTICS DATA

Further to my letter of 14 January, and the proposed analysis plan and breakdown of costs that you subsequently provided, I am pleased to confirm that the Investigation Chairman has now given his approval for this work to commence at the agreed cost of £3,800.

I apologise that it has taken until now for this work to be approved however the Investigation is subject to the Department of Health's procurement procedures. The Investigation has however extended the timetable accordingly to factor in this delay. Please let me know if a deadline of the end of May 2014 is agreeable to you.

I would be grateful if you could liaise with Hannah directly should you have any questions regarding the analysis.

Yours sincerely,

OONAGH McINTOSH
SECRETARY TO THE INVESTIGATION



RCS

ADVANCING SURGICAL STANDARDS

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London
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Ms Oonagh McIntosh
The Morecambe Bay Investigation
Park Hotel, 3rd Floor
East Cliff
Preston

26 February 2014

Dear Oonagh,

RE: ANALYSIS OF HOSPITAL EPISODE STATISTICS (HES) DATA

Thank you for your letter (dated 24 February 2014) about the use of HES data to support the Morecambe Bay Investigation, and confirming funding.

Hannah Knight and I are happy to undertake the work as described in the previous analysis plan and we will submit our report by the end of May 2014, as proposed. The invoice for the work will be submitted once we have completed the analysis and given the report to you.

Yours sincerely,

Dr David Cromwell
Director, Clinical Effectiveness Unit

Analysis Plan

TITLE: A review of clinical outcomes of maternity and neonatal care at the University Hospitals of Morecambe Bay NHS Foundation Trust (UHMB) between January 2004 and June 2013

STUDY/PROJECT: Morecambe Bay Investigation

ANALYSIS PLAN VERSION NO.: 1

PROPOSED JOURNAL: N/A

PROPOSED SUBMISSION DATE: May 2014

ANALYST: Hannah Knight

SENIOR ANALYST/SUPERVISOR: David Cromwell

1. RESEARCH QUESTION/S:

- i. Is there evidence that the standard care in UHMB's maternity and neonatal services was different from other NHS trusts during the review period on indicators derived from routine data?
- ii. Is there evidence of improvement in the maternity and neonatal indicators derived for UHMB's during the review period?
- iii. To what extent are the outcomes of maternity and neonatal care within the Trust explained by the characteristics of the population served?

2. BRIEF BACKGROUND

Between January 2004 and June 2013, there were a series of deaths of mothers and newborn babies in the maternity and neonatal services unit at Furness General Hospital. Several reviews took place during this period. However, these reviews have not given those affected confidence that all of the facts have been heard and all of the underlying issues have been resolved.

3. DATA:

- i. **DETAILS OF THE DATABASE TO BE USED:** Hospital Episode Statistics (HES)
- ii. **APPROVAL REQUIRED:** N/A – within remit of work for which CEU holds HES data
- iii. **ADMINISTRATION/ DATA STORAGE:** CEU
- iv. **SAMPLE INCLUSION CRITERIA:**
 - Women giving birth in English NHS hospitals between 1st January 2004 and 1st June 2013 (or latest data in HES extract).
 - Babies delivered in English NHS hospitals between 1st January 2004 and 1st June 2013 (or latest data in HES extract).
- v. **SAMPLE EXCLUSION CRITERIA:** Exclusion criteria will be specific to each outcome of interest below

4. OUTCOME VARIABLE(S):

i. Proposed maternal outcomes

- Mode of delivery:
 - Emergency caesarean section rate
 - Elective caesarean section rate
 - Instrumental delivery rate
 - Unassisted delivery rate
 - 'Normal' birth rate (i.e. spontaneous labour, non-instrumental vaginal birth without the use of anaesthesia or episiotomy)
- Severe maternal morbidity rate¹
- Rate of unplanned maternal readmission to hospital within 28 days

ii. Proposed neonatal outcomes

- Rate of stillbirth
 - Total stillbirth rate
 - Early neonatal death rate (<7 days)
 - Late neonatal death rate (7-28 days)
- Proportion of stillbirths and early neonatal deaths among term babies weighing >2500g
- Severe neonatal morbidity rate²
- Rate of unplanned neonatal readmission to hospital within 28 days
- Rate of unplanned neonatal readmission to hospital within 28 days for sepsis
- Rate of long-term complications associated with birth trauma (e.g. hospital readmission related to hypoxic brain injury)

iii. It might not be possible to derive all outcomes due to data quality. Some of these outcomes will require information in the maternity tail, which is not always complete. Information will be provided on the completeness of this data in addition to the information on maternal and neonatal outcomes.

- Completeness of key maternity tail fields
 - Onset of labour
 - Birth weight
 - Gestational age
 - Parity

5. EXPLANATORY VARIABLE(S) for potential confounders:

From mother:

- Maternal age, ethnicity, deprivation, parity, plurality, gestational age at delivery, existing hypertension, existing diabetes, gestational diabetes, preeclampsia/eclampsia, placenta praevia, placenta abruptio, pelvic abnormality/disproportion, oligohydramnios/polyhydramnios.

From neonate(s)

- birth weight, fetal presentation

6. CO-VARIATES:

Year of birth, NHS trust / hospital

7. PROPOSED METHOD FOR ANALYSIS:

- i. Repeated cross-sectional analyses will be performed to compare the performance of UHMB with other comparable NHS Trusts. Where appropriate, funnel plots will be used to illustrate the level of national variation and to ascertain whether the provider had a higher or lower rate on specific outcomes than expected based on its size and population characteristics
- ii. Provider rates of each outcome will be adjusted for maternal and clinical risk factors that are beyond the provider's control. A logistic regression model will be built to predict the probability of each outcome at the patient level according to their individual characteristics. These probabilities will be summed at the provider level to give the provider's predicted rate of the outcome of interest. Risk adjusted rates for each provider will be produced by dividing the provider's unadjusted rate by its predicted rate, and multiplying this ratio by the national rate.
- iii. Time series will be produced for each outcome of interest above for MB NHS trust to assess changes over time. This information will be presented using CUSUM charts.
- iv. All analyses will be performed at 2 levels: a) Trust and b) hospital.

¹ Including the following diagnoses: acute abdomen; acute renal failure; acute psychosis; cardiac arrest/failure/infarction; cerebral oedema or coma; disseminated intravascular coagulopathy; cerebro-vascular accident; major complications of anaesthesia; obstetric embolism; shock; sickle cell anaemia with crisis; status asthmaticus; status epilepticus, and uterine rupture, and the following procedures: assisted ventilation including tracheostomy; curettage in combination with a general anaesthetic; dialysis; evacuation of haematoma; hysterectomy; procedures to reduce blood flow to uterus; reclosure of disrupted cs wound; repair of bladder or cystostomy; repair of intestine; repair ruptured or inverted uterus, and transfusion of blood or coagulation factors.

² Including the following diagnoses: seizures, respiratory distress syndrome, intraventricular haemorrhage (grades 2,3 and 4), cerebral infarction, periventricular haemorrhage, birth trauma (intracranial haemorrhage paralysis due to brachial plexus injury, skull or long bone fracture), hypoxic ischemic encephalopathy, necrotising enterocolitis, broncho-pulmonary dysplasia, sepsis/septicaemia, pneumonia primary atelectasis and respiratory failure, and the following procedures: resuscitation, ventilator support (mechanical ventilation and/or CPAP), central venous or arterial catheter, transfusion of blood or blood products, pneumothorax requiring an intercostal catheter, any body cavity surgical procedure or any intravenous fluids.