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**From:** Knight, Hannah  
**Sent:** 22 April 2014 16:42  
**To:** [REDACTED]  
**Subject:** FW: The Morecambe Bay Investigation  
**Attachments:** Morcamber Bay Enquiry 180314.pdf

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**From:** [REDACTED]  
**Sent:** 19 March 2014 09:59  
**To:** Knight, Hannah  
**Cc:** Colquhoun, Richard A  
**Subject:** RE: The Morecambe Bay Investigation

Dear Hannah

Many thanks for sending your outline proposal. Please see the attached letter

Best wishes

Neena

Neena Modi  
Professor of Neonatal Medicine  
Imperial College London

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**From:** Knight, Hannah [<mailto:Hannah.Knight1@mbinvestigation.org>]  
**Sent:** 06 March 2014 16:58  
**To:** Modi, Neena  
**Subject:** RE: The Morecambe Bay Investigation

Dear Neena,

Please find attached a document describing the proposed analysis of NNRD data for the consideration of the NDAU Steering Board.

Please do not hesitate to contact me should you have any further questions.

Kind regards,

Hannah

**Hannah Knight**  
Analyst, Morecambe Bay Investigation  
3<sup>rd</sup> Floor Park Hotel  
East Cliff  
Preston  
PR1 3EA

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**From:** [REDACTED]  
**Sent:** 04 March 2014 16:44  
**To:** Knight, Hannah  
**Subject:** Re: The Morecambe Bay Investigation

Tx Hannah, we will be sending the papers out for our meeting on Monday 10th so by Friday this week would be perfect

Best wishes  
Neena

Neena Modi  
Professor of Neonatal Medicine  
Imperial College London

Sent from my iPhone

On 4 Mar 2014, at 14:48, "Knight, Hannah" <[Hannah.Knight1@mbinvestigation.org](mailto:Hannah.Knight1@mbinvestigation.org)> wrote:

Dear Neena,

I apologise for the delay in sending the protocol to you. I am hoping it will be approved at our Panel Meeting tomorrow, so it will certainly be with you this week.

Kind regards,

Hannah

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**From:** [REDACTED]  
**Sent:** 27 February 2014 12:35  
**To:** Knight, Hannah  
**Subject:** RE: The Morecambe Bay Investigation  
**Importance:** High

Dear Hannah

Are you able to give me some indication of when your protocol is likely to be available? The next meeting of the Neonatal Data Analysis Steering Board is on March 14<sup>th</sup>.

Best wishes

Neena

Neena Modi  
Professor of Neonatal Medicine  
Imperial College London

President  
The Neonatal Society

<image001.png>

A meeting of Imperial College London at BMA House, Tavistock Square, 1-5 December 2014  
[www.symposia.org.uk](http://www.symposia.org.uk)

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**From:** Modi, Neena  
**Sent:** 16 February 2014 18:02  
**To:** 'Knight, Hannah'  
**Subject:** RE: The Morecambe Bay Investigation

Dear Hannah

My personal view is that as this an NHS evaluation and as no other Trust would be identified formal approval would not be required. However I would wish to obtain the NDAU Board's advice .

We are currently awaiting HES data from the HSCIC so this availability would depend on your timescale.

Best wishes

Neena

Neena Modi  
Professor of Neonatal Medicine  
Imperial College London

President  
The Neonatal Society

<image001.png>

A meeting of Imperial College London at BMA House, Tavistock Square, 1-5 December 2014  
[www.symposia.org.uk](http://www.symposia.org.uk)

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**From:** Knight, Hannah [<mailto:Hannah.Knight1@mbinvestigation.org>]  
**Sent:** 11 February 2014 15:05  
**To:** Modi, Neena  
**Subject:** RE: The Morecambe Bay Investigation

Dear Neena,

Many thanks for your reply and confirmation of high completeness rates. We are now in the process of preparing a protocol for this analysis, which I hope to send over next week.

Since we are conducting a service evaluation on behalf of the Secretary of State for Health, rather than a research project, may I confirm whether formal approval would need to be sought from each Trust before data could be released to us? Secondly, would it be possible to have the data stripped of patient identifiers but with pseudonymised HESIDs?

Many thanks,

Hannah

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**From:** [REDACTED]  
**Sent:** 01 February 2014 14:43  
**To:** Knight, Hannah  
**Subject:** RE: The Morecambe Bay Investigation

Dear Hannah

I'd be happy to take your request to the NDAU Steering Board.

In this regard please would you send me a protocol for the proposed work in as much detail as possible, including the aim of the work, the investigating authority, the data fields, the index hospitals, and the comparator hospitals.

Research projects require Research Ethics, and Trust approval, but I presume this is not research.

We hold Caldicott Guardian approvals to utilise data for service evaluations. However if you wished us to release data to you, we would need approval from each Trust; these data would be stripped of all patient identifiers.

We hold NHS numbers solely for the purpose of linkage to HES, and could not release these to you unless you obtained approval from the Confidentiality Advisory Group of the Health Research Authority.

The data fields you listed (place of birth (available at hospital level); gestational age at birth ( weeks + days), and birth weight) have high completeness.

Please also be aware that extracting the data would require resourcing, as would any analytical/statistical support you required us to provide. Once your clear protocol is available we can cost the resource requirements.

With kind regards

Neena

Neena Modi  
Professor of Neonatal Medicine  
Imperial College London  
[REDACTED]

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**From:** Knight, Hannah [<mailto:Hannah.Knight1@mbinvestigation.org>]  
**Sent:** 29 January 2014 15:18  
**To:** Modi, Neena  
**Subject:** RE: The Morecambe Bay Investigation

Dear Professor Modi,

Thank you for your email and apologies for the delay in getting back to you.

The Investigation would be grateful if you could take our request for NNRD data to the NDAU Steering Board for their consideration.

Could you provide me with details of the regulatory approvals that will need to be sought, and confirm whether there is any way of obtaining approximate completeness rates for key variables, before submitting a formal application?

Kind regards,

Hannah

**Hannah Knight**  
Analyst, Morecambe Bay Investigation  
3<sup>rd</sup> Floor Park Hotel  
East Cliff  
Preston  
PR1 3EA

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**From:** [REDACTED]  
**Sent:** 20 January 2014 22:51  
**To:** Knight, Hannah  
**Subject:** RE: The Morecambe Bay Investigation

Dear Hannah

Apologies for the delay in getting back to you.

Please be aware that I will need to take your request to the Neonatal Data Analysis Unit Steering Board. Please note also that we would require regulatory permissions and NHS Trust approval to release any data to you. The National Neonatal Research Database contains the data fields you list but I do not know how complete they are. Extracting the data would require resourcing, as would any analytical/statistical support you required us to provide.

The analysis you require will not necessarily be straightforward. For example we do not hold denominator data (ie numbers of live and still births). The data in the National Neonatal Research Database relates to babies admitted to a neonatal unit. A further problem is that data from some Trusts includes information on babies that receive paediatric care even though they are not admitted to a neonatal unit. You will appreciate that this immediately raises the risk of non-comparable rates

Kind regards

Neena

Neena Modi  
Professor of Neonatal Medicine  
Imperial College London  
[REDACTED]

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**From:** Knight, Hannah [<mailto:Hannah.Knight1@mbinvestigation.org>]  
**Sent:** 08 January 2014 14:39

**To:** Modi, Neena  
**Subject:** RE: The Morecambe Bay Investigation

Dear Professor Modi,

To clarify, the request is for access to the NNRD data (assuming that the data fields of interest are relatively complete). The data would be used solely for the purposes of the Investigation. The intention would be for myself to perform the analysis, although perhaps we could discuss whether any expert advice/support from NDAU would be available, and how much this would cost.

If it would be useful I could arrange a teleconference with Oonagh and myself to go over the requirements in more detail.

Kind regards,

Hannah

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**From:** [REDACTED]  
**Sent:** 08 January 2014 13:58  
**To:** Knight, Hannah  
**Subject:** RE: The Morecambe Bay Investigation

Dear Hannah

Many data fields are incomplete so I am afraid I do not know how much of these data are available.

I am still also awaiting a response from Ms Oonagh McIntosh about what specifically is being requested of the Neonatal Data Analysis Unit.

Regards

Neena Modi  
Professor of Neonatal Medicine  
Imperial College London  
[REDACTED]

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**From:** Knight, Hannah [<mailto:Hannah.Knight1@mbinvestigation.org>]  
**Sent:** 08 January 2014 13:49  
**To:** Modi, Neena  
**Subject:** RE: The Morecambe Bay Investigation

Dear Professor Modi,

Thank you for your email, which has been forwarded to me. I am the analyst for the Investigation and hope to clarify our request for NNRD data.

For the purposes of the Investigation we would like to calculate the rate of admission to neonatal care for babies born within the Trust, and compare this with other Trusts (ideally after having adjusted for case-mix).

I understand that the NNRD includes demographic details, daily records of interventions and treatments, information on diagnoses and outcomes, and follow-up health status at 2 years of all babies admitted to neonatal care. Please could you confirm whether the database also includes:

- a) place of birth (and whether this is available at Trust or individual hospital level)
- b) gestational age at birth (and whether this is in completed weeks, or weeks + days)
- c) birth weight
- d) mother's NHS number, or HESID
- e) baby's NHS number, or HESID

Please could you also confirm which years the NNRD covers?

Many thanks in advance for this clarification.

Kind regards,

**Hannah Knight**  
Analyst, Morecambe Bay Investigation  
3<sup>rd</sup> Floor Park Hotel  
East Cliff  
Preston  
PR1 3EA

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**From:** McIntosh, Oonagh  
**Sent:** 06 January 2014 16:58  
**To:** Knight, Hannah  
**Subject:** FW: The Morecambe Bay Investigation

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**From:** [REDACTED]  
**Sent:** 20 December 2013 18:22  
**To:** McIntosh, Oonagh  
**Subject:** RE: The Morecambe Bay Investigation

Dear Ms McIntosh

I am writing in response to correspondence received and in particular your request to "*advise me, in writing, if the Neonatal Data Analysis Unit can agree to this request*".

I'd be grateful if you would clarify what help you require from the Neonatal Data Analysis Unit as without this detail it is difficult to know whether we would be in a position to assist. We hold information only on babies admitted to a neonatal unit; we do not hold any data on the majority of newborn babies who of course are not admitted to neonatal specialised care.

Once this clarification is received, I shall take your request to the Neonatal Data Analysis Unit Steering Board.

Kind regards

Neena Modi  
Professor of Neonatal Medicine  
Imperial College London  
[REDACTED]

[REDACTED]

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**From:** Correspondence MB [<mailto:correspondence@mbinvestigation.org>]

**Sent:** 19 December 2013 12:24

**To:** Modi, Neena

**Cc:** Neonatal Data Analysis Unit; Knight, Hannah; Roberts, Paul; McIntosh, Oonagh

**Subject:** The Morecambe Bay Investigation

Dear Professor Modi

Please find attached a letter from Oonagh McIntosh, Secretary to the Investigation, along with our Terms of Reference.

Your sincerely

[REDACTED]  
Secretariat Support Assistant, Morecambe Bay Investigation

Third Floor - Park Hotel, East Cliff, Preston, PR1 3EA

E: [REDACTED]@mbinvestigation.org | T: 01772 536376

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# **THE MORECAMBE BAY INVESTIGATION**

Chaired by Dr Bill Kirkup CBE

## **Protocol for the consideration of the Neonatal Data Analysis Unit Steering Board**

### **Summary**

This document sets out a formal request for access to data from the National Neonatal Research Database (NNRD) to inform an independent service evaluation, namely the Morecambe Bay Investigation. Below is an outline of the Investigation's remit and the proposed data analysis.

### **Background**

The University Hospitals of Morecambe Bay NHS Foundation Trust (UHMBT) has been the subject of scrutiny since at least 2009. Initial concerns arose following a high number of serious untoward incidents in the maternity and neonatal services provided by Trust. The families of those who died under the care of the Trust have persistently sought a full and independent investigation into these services.

On 12 September 2013, the Secretary of State for Health announced an independent investigation into the management, delivery and outcomes of care provided by the Maternity and Neonatal services of UHMBT from January 2004 – June 2013, chaired by Dr Bill Kirkup CBE.

The Investigation's Terms of Reference are:

1. To review the outcomes for mothers and babies that occurred during this time, including maternal and neonatal deaths that occurred in the Trust and in any other institutions to which patients were transferred;
2. To review the Trust Board's actions and governance procedures in response to untoward incidents such as the deaths of mothers and babies, including:
  - a) The Board's processes for responding to serious untoward incidents (SUIs); and
  - b) The relationship and communication between the Trust and
    - Patients and families
    - GPs and community ante-natal midwifery services
    - Commissioners, predominantly in the two local PCTs, Cumbria PCT and North Lancashire PCT, their predecessor PCTs, and successor CCGs
    - The North West Strategic Health Authority
    - Regulators – including Monitor, CQC, and the Healthcare Commission.
    - Public Health services
    - Other Trusts where mothers and babies were transferred
    - Any other relevant organisations.

c) Relevant investigations published by the Parliamentary and Health Service Ombudsman.

3. To review the Trust Board's responses to, and any subsequent actions taken following receipt of, the following reports:

- Monitor's review of the Trust's application for FT status (April 2010), October 2010
- The Fielding Report, August 2010
- Central Manchester University Hospital Diagnostic Review, December 2011
- PWC Governance Review, February 2012
- Gold Command Stocktake, April 2012
- Care Quality Commission (CQC) Investigation Report, July 2012
- Nursing and Midwifery Council (NMC) Review, July 2012;
- The NHS Litigation Authority's Clinical Negligence Scheme for Trusts (CNST) reports

4. To make findings as to the adequacy of the actions taken at the time by the Trust to mitigate concerns over safety;

5. In light of this, to assess and make findings as to the Trust's ability to discharge its duties in delivering maternity services; and

6. To make recommendations on the lessons to be learned for both the Trust and the wider NHS to secure the delivery of high quality care.

#### **Request for National Neonatal Research Database**

Under the first term of reference, the Investigation will review neonatal outcomes at the Trust during the period of investigation. This includes outcomes among babies born at the Trust but transferred elsewhere for specialised neonatal care.

The Investigation has access to Hospital Episode Statistics (HES) data covering the period it is reviewing, and is analysing the outcomes among babies born in the Trust using information available in HES birth records. However, the Investigation understands that the NNRD holds considerably more detailed information on babies admitted to English neonatal units since 2007, including: place of birth, demographic details, birthweight, gestational age, daily records of interventions and treatments, information on diagnoses and outcomes, and follow-up health status at 2 years.

Ideally, the Investigation would like to access information on neonatal outcomes for babies born at the Trust and transferred to neonatal care, broken down by hospital of birth. The Trust comprises 3 acute hospitals:

- Furness General Hospital (~1000 deliveries/year; neonatal unit: 5 bed level 1)
- Royal Lancaster Infirmary (~2000 births/year; neonatal unit: 10 bed level 2)
- Westmorland General Hospital (<500 deliveries; no neonatal unit)

Babies requiring specialist or level 3 neonatal care are typically transferred to one the following hospitals: Royal Bolton, Royal Preston, Lancashire Women and Newborn Centre (Burnley), Liverpool Women's Hospital, Royal Manchester Children's Hospital, St Mary's Manchester, or the Royal Victoria (Newcastle).

The Investigation wishes to use data held in the NNRD to verify information provided by other organisations, in particular:

- How many babies born at each of the three hospitals within the Trust were admitted to neonatal care during the period of investigation, and which hospitals were they admitted to?
- How many of these babies were term newborns weighing >2500g?
- How many of these babies were admitted with symptoms associated with substandard intrapartum care, e.g. birth asphyxia?
- How many of these babies subsequently died?

In order to establish whether the Trust was an outlier for particular neonatal outcomes, the Investigation would also like to compare the outcomes of babies born at the Trust with those of babies born in other NHS Trusts.

The Investigation understands that without Section 251 approval the NNRD data is available in anonymised form only. However, if it were possible to link the NNRD to HES using the pseudonymised HESID, this would enable a more thorough analysis and provide denominator data for calculating incidence rates and rates of admission to neonatal care to enable comparison between units.

## **Proposal**

The Investigation has appointed an analyst to review the statistical evidence to be considered in conjunction with other forms of evidence that are pertinent and relevant to the Investigation. If the NDAU Steering Board agrees in principle to NNRD data being used to inform the Morecambe Bay Investigation, two options for conducting this work could be considered:

- 1) The Investigation's analyst is given access to the NNRD database and performs the analysis, with limited support from NDAU staff.
- 2) The Investigation commissions the NDAU to perform the analysis on its behalf.

If the NDAU Steering Board prefers the first option, please provide details on whether the Unit has a standard approach to formalising such requests by means of a Data Sharing Agreement or Memorandum of Understanding.

If the NDAU Steering Board prefers the second option, the Investigation would require a detailed list of the planned analyses, the methods that will be employed, a breakdown of the estimated costs and a time scale for the delivery of this work. The planned analyses would then have to be agreed by the Investigation's Chairman and the estimated costs would be considered by the Secretary to the Investigation.

**Hannah Knight**  
Analyst, Morecambe Bay Investigation  
3<sup>rd</sup> Floor Park Hotel  
East Cliff  
Preston PR1 3EA

Match 18<sup>th</sup> 2014

Dear Hannah

**Morecambe Bay Enquiry**

Thank you for your recent emails and the protocol for consideration by the Neonatal Data Analysis Unit (NDAU) Steering Board. The Board considered this at their meeting on March 14.

The NDAU are able to provide data from 2010 to 2013 inclusive from the National Neonatal Research Database. Data are held from 2007, but these are in a different format and would require merging with later data, which would require substantial capacity to undertake, and is not recommended.

Data in the National Neonatal Research Database are extracts from a real-time patient management system and are held with Caldicott Guardian and other regulatory approvals. Please be aware that the NDAU cannot be responsible for the quality or completeness of data. No patient identifiers would be released.

The NDAU do not receive data from Westmorland General Hospital. Data from Furness General Hospital and Royal Lancaster Infirmary would include hospital identifiers, but data for the rest of England, provided for comparison would be stripped of unit and network identifiers; designation (i.e. NICU, LNU, SCBU) would be retained.

The NDAU team would be happy to work with the Morecambe Bay team to define the precise data to be extracted but would not be in a position to undertake the analysis.

A realistic time frame would need to be established and costs for the data extraction agreed.

I hope you will find this response helpful.

Sincerely

[REDACTED SIGNATURE]

**Neena Modi**  
Professor of Neonatal Medicine  
Imperial College London

Chair  
NDAU Steering Board

# **THE MORECAMBE BAY INVESTIGATION**

Chaired by Dr Bill Kirkup CBE

Professor Neena Modi  
Neonatal Data Analysis Unit  
Division of Medicine  
Imperial College London  
Academic Department of Neonatal Medicine  
4<sup>th</sup> Floor, Chelsea & Westminster Hospital  
369 Fulham Road  
London SW10 9NH

3<sup>rd</sup> Floor  
Park Hotel  
East Cliff  
Preston  
Lancashire  
PR1 3EA

10 July 2014

Dear Professor Modi,

## **ACCESS TO THE NATIONAL NEONATAL RESEARCH DATABASE**

Thank you for your letter of 2 April 2014 regarding the estimated timescale and cost of the analysis of NNRD data to support the Morecambe Bay Investigation.

Unfortunately due to the Investigation's timescale and the uncertainty around the completeness of the NNRD data, the Investigation will not be pursuing this analysis further.

As the Investigation is reporting to the Secretary of State for Health no later than November 2014, the Panel requires all statistical analyses to be completed well in advance of this date so that the results can be used to inform the interviews taking place over the summer and in September.

I apologise that it has taken until now for this decision to be made and communicated to you. The Investigation has been actively gathering evidence from a large number of organisations and it is now felt that sufficient information on neonatal admissions among babies born in the Trust is available from alternative sources.

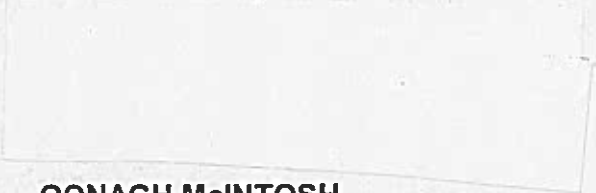
Telephone: 01772 536376

Email: [correspondence@mbinvestigation.org](mailto:correspondence@mbinvestigation.org)

*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*

Thank you again for taking the time to consider the Investigation's request and for the advice you were able to offer.

Yours sincerely,



**OONAGH McINTOSH**  
**SECRETARY TO THE INVESTIGATION**