THE MORECAMBE BAY INVESTIGATION

Chaired by Dr Bill Kirkup CBE

Sir Andrew Dillon Chief Executive National Institute for Health and Care Excellence 10 Spring Gardens London SW1A 2BU 3rd Floor Park Hotel East Cliff Preston Lancashire PR1 3EA

17th January 2014

Telephone: 01772 536376 Email: correspondence@mbinvestigation.org

Dear Sir Andrew.

DOCUMENTS AND EVIDENCE REQUIRED BY THE MORECAMBE BAY INVESTIGATION

As you will be aware the Secretary of State for Health announced the terms of reference of the University Hospitals of Morecambe Bay NHS Foundation Trust (UHMBT) Maternity and Neonatal Services Investigation (the Morecambe Bay Investigation) on 12 September. I have enclosed a copy of the terms of reference with this letter for your information.

Dr Bill Kirkup CBE has been appointed as Chairman of the independent Investigation and is seeking the full co-operation of you and your organisation.

Although the Chairman may communicate directly with you when appropriate to do so from time to time, you may prefer to have a colleague to be the main day to day point of contact with the investigation. It would assist the work of the Investigation if you could advise me as the Secretary to the Investigation, of their name and contact details. Arrangements will then be made to ensure that discussions regarding administrative matters are conducted directly with your nominee.

The Investigation is now collecting evidence in respect of its terms of reference.

This letter sets out the evidence required from the National Institute for Health and Care Excellence (NICE). Further requests may be made at a later date.

The Investigation's Documents and Evidence Manager (DEM), Paul Roberts, or the Assistant Documents and Evidence Manager (ADEM) will be your principle points of contact in relation to evidence management.

The Investigation would prefer to receive evidence electronically in one of the following formats:

Searchable PDF

- Word
- Excel

Should this not be possible, please contact Paul or to discuss alternative ways in which the evidence can be made available to the Investigation.

Following discussions with officials in the Department of Health, the Investigation has been advised that, for a period of time covered by the Investigation's terms of reference, NICE was the body responsible for developing and disseminating guidance on matters of interest to it, and it should make contact with you directly.

Management of evidence by the Investigation

The Investigation recognises that NICE will be concerned to know how material it is being asked to provide to the Investigation will be managed. It will therefore be helpful for you to know that material sought by and supplied to the Morecambe Bay Investigation from interested organisations and the families of those involved will be viewed and accessed by Investigation staff and the Investigation Panel only.

All Investigation staff, including the Panel, will view the material via a secure internet based database to which access will be controlled by the Investigation's Documents and Evidence Management Team and all Investigation personnel, including Panel members, are required to sign and adhere to the terms of a confidentiality undertaking.

Material and\or documents supplied to the Investigation will be collected from, or derived from, official files that are the property of interested organisations and\or individuals and will be considered by the Investigation as "working papers".

Working papers will be either returned to the relevant interested organisation\family at the end of the Investigation or destroyed by the Investigation and a record of all document destruction will be retained.

The Investigation has applied to the Information Commissioner for Data Protection Act Registration and fully understands its responsibilities holding evidence supplied by interested organisations.

Material and\or documents supplied to and considered by the Investigation will not be provided or shown to any witness in advance of their attendance, by the Investigation. Witnesses will be advised in advance of their attendance what specific topics or areas the Panel wish to ask them about and which of the Investigations specific term(s) of reference they are being invited to provide evidence in respect of.

Should any witness wish to be reacquainted with any material and\or document(s) prior to attending the Investigation for an interview or to give evidence, they will be advised by the Investigation to liaise with their employer, or former employer, to make any necessary arrangements for them to undertake any such preparation.

I trust that being made aware at this early stage of the protocol the Investigation has adopted regarding document management will assist NICE in providing material as swiftly as possible.

The evidence required for the Investigation from NICE is set out at Annex A, and should be submitted to the Investigation within 21 working days of the date of this letter.

I anticipate that your organisation will hold evidence from the period of time the National Institute for Clinical Excellence was the body responsible for these matters. However, should that not be the case, I would be grateful if you could advise the Investigation where that evidence might be obtained.

Once the evidence has been examined, the Chairman will decide who oral evidence should be heard from. Can I remind you that it would be helpful, even at this early stage, if you would advise your staff accordingly and if you would also make contact with any staff member who has retired or left your organisation. To ensure the smooth running of the Investigation it will be important to ensure we have up to date contact details for those who may be asked to give oral evidence.

If you have any further queries regarding the evidence being requested, please contact:

Paul Roberts:

T: 01772 536401

E: paul.roberts@mbinvestigation.org

T: 01772 536390

mbinvestigation.org

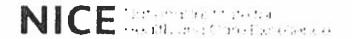
Yours sincerely,

OONAGH McINTOSH
SECRETARY TO THE INVESTIGITON

Enc: MBI Terms of reference

Annex A

- 1. The evidence required from NICE should cover the period from 1 January 2004 to 30 June 2013, and should include any information that was known and is pertinent to the Investigation.
- 2. Any NICE Clinical Guidance that relates to maternity and/or neonatal care.
- 3. Any NICE Quality Standards that relate to maternity or neonatal care.
- 4. Any correspondence between the Trust and NICE relating to Quality Standards and/or Clinical Guidance.
- 5. Any correspondence between NICE and the North West Strategic Health Authority relating to Quality Standards and/or Clinical Guidance.
- 6. Any correspondence between NICE and the Morecambe Bay Primary Care Trust or North Lancashire Primary Care Trust relating to Quality Standards and/or Clinical Guidance.
- 7. Any other material that NICE considers would assist the independent investigation address its terms of reference in full.



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Oonagh McIntosh
The Morecambe Bay Investigation
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Park Hotel
East Cliff
Preston
Lancashire
PR1 3EA

19 February 2014

Dear Oonagh McIntosh,

Sir Andrew Dillon has asked me to respond on his behalf to your request to provide evidence to support the Morecambe Bay Investigation. We have collated a number of documents which we hope will be helpful to you, and are happy to provide further assistance if required.

Clinical guidance and quality standards relating to maternity/neonatal care.

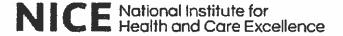
In regards to relevant guidance and quality standard documents, we have provided links to those that are available on our website. As your Investigation spans 1 January 2004 to 30 June 2013, we have attached copies of guidance documents that would have been current during this timeframe, but which have now been superseded and therefore no longer available on the NICE website.

Current clinical guidelines

Antenatal care (CG62), Issued: March 2008,

Antenatal and postnatal mental health (CG45), Issued: February 2007, link to pdf document

Caesarean section (CG132), Issued: November 2011, link to pdf document
Diabetes in pregnancy (CG63), Issued: March 2008, link to pdf document
Induction of labour (CG70), Issued: September 2007, link to pdf document
Intrapartum care (CG55), Issued: September 2007, link to pdf document
Multiple pregnancy (CG129), Issued: September 2011, link to pdf document
Postnatal care(CG37), Issued: July 2006, link to pdf document
Pregnancy and complex social factors (CG110), Issued: September 2010, link to pdf
document



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Superseded clinical guidelines attached

Induction of labour (D guideline) issued in 2001, superseded by Induction of labour (CG70)

Antenatal care CG6, superseded by Antenatal care (CG62)

Electronic fetal monitoring (C guideline) Issued in 2001, superseded by Intrapartum care (CG55)

Caesarean section CG13 issued in 2004, superseded by Caesarean section (CG132)

Quality standards

Antenatal care

Antibiotics for neonatal infection

Caesarean section

Hypertension in pregnancy

Induction of labour

Multiple pregnancy

Neonatal jaundice

Pain and bleeding in early pregnancy

Patient experience in adult NHS services

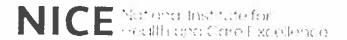
Postnatal care

Specialist neonatal care

Correspondence between NICE and Morecambe Bay Hospital Trust, North West Strategic Health Authority, Morecambe Bay Primary Care Trust and North Lancashire Primary Care Trust

You have asked for correspondence that we hold between NICE and Morecambe Bay Hospital Trust, North West Strategic Health Authority, Morecambe Bay Primary Care Trust or North Lancashire Primary Care Trust. The type of correspondence we could potentially hold includes;

- Consultation responses received by our clinical guideline and quality standard teams.
- General enquiries received by our enquiry handling team relating to guidance and quality standards
- Correspondence with the NICE Implementation Consultants for the North West region



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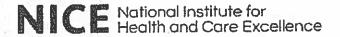
We have checked with all relevant teams and can confirm we don't hold any consultation responses for maternity/neonatal guidance or quality standards from any of the above organisations. We have one general enquiry relating to the specialist neonatal care quality standard dated 29 October 2010 and this is attached as 'Appendix A - NICE response to QS enquiry from Morecambe Bay Hospital Nov 2010.'

We do hold a number of pieces of correspondence between the Implementation Consultant for the North West region and the above organisations. Full text is provided in the spreadsheet, 'Appendix B – NICE email correspondence 2009 to 2014'. We have also identified an additional internal email relating to a meeting with Westmorland Hospital, this is attached as 'Appendix C – NICE internal email regarding Westmorland meeting April 2013'

The role of the Implementation Consultant is to work with local organisations to help put our guidance into practice. As part of this role the Implementation Consultant for the North West region has had a number of meetings with staff from the above organisations. Feedback from these meetings and points of interest for NICE are documented in our customer relationship management (CRM) database. Although these records do not constitute correspondence, as you have requested any other information we think might be pertinent to the Investigation, we have included full details of meeting feedback in the spreadsheet, 'Appendix D – Implementation meeting feedback 2006 to 2014.'

Please be aware that the correspondence and meeting records we have provided are an internal resource for NICE and we are providing this information on a confidential basis. Should there be a requirement to release this information more widely, we would need to consider our responsibilities under the Data Protection Act and apply redactions to the personal and sensitive data included in these documents.

It is also important to note that the spreadsheet of correspondence does not represent a complete record of all correspondence between the above organisations and NICE Implementation Consultants between 2004 and 2013. We are only able to provide details of correspondence that has been saved to our CRM database or which current Implementation Consultants have within their own email records. The CRM database was introduced in 2011 and whilst some email correspondence was added retrospectively, it is likely that some correspondence before this date will not have been kept. However our Implementation Consultants would be more than



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happy to answer any further questions you may have about our contact with the organisations within the Investigation remit.

Yours sincerely

Communications Executive