

---

## DIRECTIONS

---

# The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018

The Secretary of State for Health and Social Care, in exercise of the powers conferred by sections 7, 8, 272(7) and (8) and 273(1) of the National Health Service Act 2006(a), makes the following Directions:

### Application, citation, commencement and interpretation

1.—(1) These Directions may be cited as the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018 and come into force on 30th April 2018.

(2) In these Directions—

“the 2006 Act” means the National Health Service Act 2006;

“the Authority” means the National Health Service Trust Development Authority, a special health authority established pursuant to section 28 of the 2006 Act(b);

“the Chief Investigator” has the meaning given in the HSIB Directions;

“the Each Baby Counts Report” means the “Each Baby Counts 2015 Full Report” published by the Royal College of Obstetricians and Gynaecologists and dated October 2017(c);

“HSIB” means the Healthcare Safety Investigation Branch of the Authority established pursuant to the HSIB Directions;

“the HSIB Directions” means the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 dated 24th March 2016(d);

“provider” has the meaning given in HSIB Directions;

“qualifying maternity case” means —

(a) a case which involves a baby which falls within one of the categories of “eligible babies”(e) as described in the Each Baby Counts Report; or

- 
- (a) 2006 c.41. Section 7 was amended by section 21 of the Health and Social Care Act 2012 (c.7) (“the 2012 Act”). Section 8 was amended by section 55(1) of, and paragraph 5 of Schedule 4 to, the 2012 Act. Other amendments have been made that are not yet in force. By virtue section 271(1) of the 2006 Act the powers exercised by the Secretary of State in making these Directions are exercisable only in relation to England.
- (b) . Section 28 was amended by Schedule 4, paragraph 13, to the 2012 Act. The National Health Service Trust Development Authority is established by the National Health Service Trust Development Authority (Establishment and Constitution Order 2012, S.I. 2012/901, amended by S.I. 2013/235 and S.I.2013/260.
- (c) Each Baby Counts 2015 Full Report, Royal College of Obstetricians and Gynaecologists, London: RCOG, 2017. Available online: [www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/each-baby-counts/ebc-2015-report/](http://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/each-baby-counts/ebc-2015-report/). A hard copy can be obtained by writing to the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU.
- (d) The HSIB Directions directs the Authority to establish and provide for the operation of a branch of the Authority known as the Healthcare Safety Investigations Branch to carry out investigations into safety incidents in the NHS. Available online: <https://www.gov.uk/government/publications/nhs-trust-development-authority-directions-2016>. A hard copy can be obtained by writing to the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU.
- (e) “Eligible babies” include all term babies born following labour who have one of the following outcomes; intrapartum stillbirth, early neonatal death or severe brain injury diagnosed in the first seven days of life and who fall within one of the classes of case described under these headings in the Each Baby Counts Report (page 20). For the definition of “labour” see page 21.

- (b) a case of direct or indirect maternal death as defined in the MBRRACE report, “Saving Lives, Improving Mothers’ Care” dated December 2016<sup>(a)</sup>;
- (3) These Directions are given to the Authority and relate to the following matters —
  - (a) the Secretary of State’s function under section 1(1) of the 2006 Act of continuing the promotion in England of a comprehensive health service designed to secure improvement in the physical and mental health of the people of England, and the prevention, diagnosis and treatment of physical and mental illness<sup>(b)</sup>;
  - (b) the Secretary of State’s function under section 2 of the 2006 Act of doing anything which is calculated, conducive or incidental to, the discharge of any function conferred on the Secretary of State by the 2006 Act;
  - (c) the Secretary of State’s duty under section 1A of the 2006 Act to exercise his functions in relation to the health service with a view to securing continuous improvement in the quality of services provided for or in connection with the prevention, diagnosis or treatment of illness<sup>(c)</sup>.

### **Additional investigatory functions for the Healthcare Safety Investigation Branch**

2.—(1) The Authority is directed to require HSIB to carry out such additional investigatory functions as are provided for in these Directions in order to assist in the discharge of the Secretary of State’s functions described in paragraph 1(3), and in particular, the Secretary of State’s duty described in paragraph 1(3)(c).

(2) The additional investigatory functions referred to in these Directions are separate from the investigatory functions which the Authority is directed to carry out under paragraph 5 of HSIB Directions.

(3) The Authority is directed to ensure that HSIB has the skills necessary to carry out the additional investigatory functions.

(4) In carrying out the additional investigatory functions, the ‘safe space principle’ as described at paragraph 6(1) of HSIB Directions does not apply and the following provisions of HSIB Directions also do not apply—

- (a) paragraph 5 (investigatory functions);
- (b) paragraph 6 (safe space);
- (c) paragraph 7 (investigation principles);
- (d) paragraph 8 (investigation process and reports).

(5) Notwithstanding paragraph (4), the provisions of HSIB Directions otherwise apply to HSIB when carrying out the additional investigatory functions.

### **Investigation by HSIB on referral of qualifying maternity cases**

3.—(1) HSIB must investigate each qualifying maternity case referred to it.

(2) The investigation must seek to—

- (a) establish the facts leading to the outcome that makes the case a qualifying maternity case;
- (b) set out the sequence of events that led to that outcome;

---

(a) Page 9 of Knight M, Nair M, Tuffnell D, Kenyon S, Shakespeare J, Brockelhurst P, Kurinczuk JJ (Eds.) on behalf of MBRRACE-UK, Saving Lives, Improving Mothers’ Care - Surveillance of maternal deaths in the UK 2012-14 and lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2009-14. Oxford: National Perinatal Epidemiology Unit, University of Oxford 2016. Available online: <http://www.npeu.ox.ac.uk/downloads/files/mbrrace-uk/reports/MBRRACE-UK%20Maternal%20Report%202016%20-%20website.pdf>. A hard copy can be obtained by writing to the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU.

(b) Section 1(1) of the 2006 Act was substituted by section 1 of the 2012 Act.

(c) Section 1A of the 2006 Act was inserted by section 2 of the 2012 Act.

- (c) identify all contributory factors that led to that outcome;
  - (d) consider any specific concerns raised by or on behalf of the mother and on behalf of the baby and, where appropriate, concerns raised by any members of the mother and baby’s family;
  - (e) consider any specific concerns raised by any person, employed or otherwise engaged by the provider, who was involved in the care the mother or baby received or by any other person as HSIB thinks appropriate; and
  - (f) consider how its findings compare to the “Key Recommendations for Care” in Every Baby Counts<sup>(a)</sup> and in any other relevant guidance issued by the National Institute for Health and Care Excellence<sup>(b)</sup>.
- (3) HSIB must consult and seek evidence or information from—
- (a) the mother, or where the mother is deceased or otherwise unable to engage with the investigation, the person or persons as appear to HSIB to best represent the interests of the mother and, where appropriate, the baby;
  - (b) any members of the mother and baby’s family as HSIB thinks appropriate;
  - (c) any person, employed or otherwise engaged by the provider, who was involved in the care the mother or baby received;
  - (d) such other persons as HSIB thinks necessary for the purposes of carrying out the investigation.

**Reports**

4.—(1) HSIB must, within a reasonable period of time, produce a report on the matters set out in sub-paragraph 3(2) and, as far as reasonably practicable, such period should not exceed six months from the date on which the qualifying maternity case in question was referred to it.

(2) Before producing the report referred to in sub-paragraph (1), HSIB must provide a draft of that report, including a draft summary of the facts, in confidence to —

- (a) the mother or, where the mother is deceased or otherwise unable to engage with the investigation, the person or persons as appear to HSIB to best represent the interests of the mother, and where appropriate, the baby;
- (b) any members of the mother and baby’s family as HSIB thinks appropriate;
- (c) the provider concerned;
- (d) any person, employed or otherwise engaged by the provider, who was involved in the care the mother or baby received as HSIB thinks appropriate;

(3) Any person to whom a copy of the draft report and summary has been provided pursuant to sub-paragraph (2), must be given such period of time as HSIB considers reasonable to comment on the accuracy of, and conclusions reached in, the report.

(4) Before finalising the report, HSIB must take into account such comments as are provided pursuant to sub-paragraph (3) and make such revisions to the draft report as HSIB considers appropriate to achieve the goals set out in paragraph 3(2).

(5) On completing the report, HSIB must provide a copy of that report to-

- (a) the provider;
- (b) the mother, or
- (c) where the mother is deceased or otherwise unable to engage with the investigation, to any person that appears to HSIB to best represent the interests of the mother and, where appropriate, the baby.

---

(a) see pages 16-18 of the Every Baby Counts Report.

(b) the National Institute for Health and Care Excellence (“NICE”) was established by section 232 of the 2012 Act.

(6) HSIB may provide a copy of the report to any members of the mother and baby’s family as HSIB thinks appropriate.

**Further conclusions arising from the investigation**

5. At the end of each investigation HSIB must—

- (a) consider whether any of the conclusions drawn from the facts of the case or the contributing factors indicate any deficiencies in practice that should be rectified at the provider concerned or more widely;
- (b) disseminate any such conclusions to the provider or providers more widely, or to any relevant national bodies responsible for healthcare in England, who, in HSIB’s view, may benefit from knowing the conclusions;
- (c) alert the clinical commissioning group(a) or groups concerned or as the case may be the National Health Service Commissioning Board (b) to any conclusions reached under this paragraph about deficiencies in practice that should be rectified;
- (d) provide the mother, or, where the mother is deceased or otherwise unable to engage with the investigation, such person as appears to HSIB to best represent the interests of the mother and, where appropriate the baby, with information about any deficiencies in practice which have been disseminated to any provider or other body in accordance with sub-paragraph (b) or (c).

**Publication of thematic report**

6.—(1) The Chief Investigator must publish a report in accordance with sub-paragraph (3) on the investigations carried out by HSIB under these Directions.

(2) The report referred to in sub-paragraph (1) must—

- (a) draw together the overarching themes of the investigations;
- (b) aggregate points of learning from the investigations;
- (c) where appropriate, make recommendations for the purposes of securing continuous improvement in the quality of services provided as part of the health service;

(3) The first of the reports referred to in sub-paragraph (1) must be published by HSIB no later than 12 months after the date on which the first qualifying maternity case is referred to HSIB under these Directions and subsequent reports published under sub-paragraph (1) must be published at least once in each 12 month period starting from the date of publication of the previous report under that sub-paragraph.

Signed by authority of the Secretary of State for Health and Social Care



Date of signing: 23<sup>rd</sup> April 2018

William Vineall  
an official of the Department of Health and Social Care  
and member of the Senior Civil Service

---

(a) Clinical commissioning groups are defined at section 1I of the National Health Service Act 2006 (c.41) and commission health services from providers.  
(b) The National Health Service Commissioning Board (“the Board”) was established by section 1H of the 2006 Act, as inserted by section 9(1) of the Health and Social Care Act 2012 (c. 7). The Board is known as NHS England.