Directions revoked

The directions which conferred the HSIB’s maternity investigation functions on NHS England have now been fully revoked.

The HSIB's maternity investigations programme transitioned to the Care Quality Commission (CQC) on 1 October 2023. The Care Quality Commission (Maternity and Newborn Safety Investigation Programme) Directions 2023 confer the HSIB’s maternity investigation programme to CQC. The new directions allow for the continuation of independent, single case investigations.

The NHS England (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2022

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

Citation, commencement and interpretation

1.—(1) These Directions may be cited as the NHS England (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2022 and come into force on 1st July 2022.

(2) In these Directions—

"the 2006 Act" means the National Health Service Act 2006;

"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(**b**);

"the HSIB" means the Healthcare Safety Investigation Branch of NHS England established pursuant to the HSIB Directions;

"the HSIB Directions" means the NHS England (Healthcare Safety Investigation Branch) Directions 2022(**c**);

"integrated care board" has the function of arranging for the provision of services for the purposes of the health service in England in accordance with the 2006 Act(**d**);

"NHS England" is responsible for the commissioning of health care services in England and is the regulator of NHS providers(**e**);

"provider" has the meaning given in the HSIB Directions;

"qualifying maternity case" means—

(a) a case which involves a baby which falls within one of the categories of "eligible babies" as described on page 20 and 21 in the Each Baby Counts Report; or

(**a**) 2006 (c. 41). Section 7C was inserted by section 44 of the Health and Care Act 2022 (c. 31).

(**b**) 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/. A hard copy can be obtained by writing to the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU.

(**c**) The HSIB Directions direct NHS England to establish and provide for the operation of a division of NHS England to be known as the Healthcare Safety Investigation Branch to carry out investigations into safety incidents in the NHS. Available online. A hard copy can be obtained by writing to the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU.

(**d**) Section 1I of the National Health Service Act 2006 as inserted by section 18 of the Health and Care Act 2022.

(**e**) NHS England was formerly known as the National Health Service Commissioning Board/NHS Commissioning Board. It was renamed by section 1 of the Health and Care Act 2022. NHS England has regulatory functions as well as functions in relation to commissioning, as section 33 of that Act abolished the former NHS provider regulator, Monitor, and transferred its functions to NHS England.

(b) a case of direct or indirect maternal death as defined in the MBRRACE report, "Saving Lives, Improving Mothers' Care" dated December 2016(**a**).

Scope

2.—(1) These Directions are given to NHS England 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 in the prevention, diagnosis and treatment of physical and mental illness;

(b) the Secretary of State's duty under section 1A of the 2006 Act to exercise the Secretary of State's functions in relation to the health service with a view to securing continuous improvement in the quality of services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness;

(c) the Secretary of State's function under section 2 of the 2006 Act of doing anything which is calculated to facilitate, or is conducive or incidental to, the discharge of any function conferred on the Secretary of State by the 2006 Act.

Additional investigatory functions for the Healthcare Safety Investigation Branch

3.—(1) NHS England is directed to require the HSIB to carry out such additional investigatory functions as are provided for in these Directions in order to assist in discharging the Secretary of State's functions described in direction 2(1) and, in particular, the duty described in direction 2(1)(b).

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

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

(4) In carrying out the additional investigatory functions, the safe space principle does not apply and the following provisions of the HSIB Directions also do not apply—

(a) direction 5 (investigatory functions);

(b) direction 6 (safe space);

(c) direction 7 (investigation principles);

(d) direction 8 (investigation process and reports).

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

(**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: https://www.npeu.ox.ac.uk/assets/downloads/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.

Investigation by the HSIB on referral of qualifying maternity cases

4.—(1) The 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;

(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 the HSIB thinks appropriate; and

(f) consider how its findings compare to the "Key Recommendations for Care" in Every Baby Counts(**a**) and in any other relevant guidance issued by the National Institute for Health and Care Excellence(**b**).

(3) The 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 the 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 the HSIB thinks appropriate;

(c) any person, employed or otherwise engaged by the provider, who was involved in the care the mother or baby received; and

(d) such other persons as the HSIB thinks necessary for the purposes of carrying out the investigation.

Reports

5.—(1) The HSIB must, within a reasonable period of time, produce a report on the matters set out in direction 4(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 paragraph (1), the 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 the 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 the HSIB thinks appropriate;

(c) the provider concerned; and

(d) any person, employed or otherwise engaged by the provider, who was involved in the care the mother or baby received as the HSIB thinks appropriate.

(**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 Health and Social Care Act 2012 (c. 7).

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

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

(5) On completing the report, the 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 the HSIB to best represent the interests of the mother and, where appropriate, the baby.

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

Further conclusions arising from the investigation

6. At the end of each investigation the 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 the HSIB's view, may benefit from knowing the conclusions;

(c) alert the integrated care board or groups concerned or, as the case may be, NHS England to any conclusions reached under direction 5 about deficiencies in practice that should be rectified; and

(d) provide the mother, or, where the mother is deceased or otherwise unable to engage with the investigation, such person as appears to the 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 paragraph (b) or (c).

Publication of thematic report

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

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

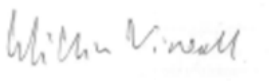
(a) draw together the overarching themes of the investigations;

(b) aggregate points of learning from the investigations; and

(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 paragraph (1) must be published by the HSIB no later than 12 months after the date on which the first qualifying maternity case is referred to the HSIB under these Directions and subsequent reports published under 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 paragraph.

Signed by authority of the Secretary of State



William Vineall
A member of the Senior Civil Service
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Date: 30th June 2022