NATIONAL HEALTH SERVICE, ENGLAND

The Care Quality Commission (Maternity and Newborn Safety Investigation Programme) Directions 2023

The Secretary of State makes these Directions in exercise of the powers conferred by sections 7C(1) and (5), 272(7) and (8) and 273(1) of the National Health Service Act 2006(**a**).

Citation, commencement and interpretation

1.—(1) These Directions may be cited as The Care Quality Commission (Maternity and Newborn Safety Investigation Programme) Directions 2023 and come into force on 1st October 2023.

(2) In these Directions—

"the 2018 Directions" means the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018(**b**);

"the 2022 Directions" means the NHS England (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2022(**c**);

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

"the Commission" means the Care Quality Commission established by section 1 of the Health and Social Care Act 2008(**d**);

"provider" means any body or person, other than an integrated care board or NHS England, engaged in the provision of goods or services for the purposes of the health service in England;

"qualifying maternity case" means a case that meets the criteria set out in the Schedule.

(3) These Directions are given to the Commission and relate to the following matters provided for in the Act—

(a) the Secretary of State's function under section 1(1) of the Act(**e**) 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;

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

(**b**) The National Health Service Trust Development Authority (Healthcare Safety Investigations Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018 ("the 2018 Directions" were signed on 23rd April 2018 and revoked by the NHS England (Healthcare Safety Investigation Branch) Directions 2022 (signed on 30th June 2022) on 1st July 2022. A copy of the 2018 Directions is available online: https://www.gov.uk/government/publications/nhs-trust-development-authority-hsib-maternity-investigations-directions-2018. Hard copies of these directions can be requested from the Quality, Patient Safety and Maternity Team, Department of Health and Social Care, Quarry House, Quarry Hill, Leeds LS2 7UE.

(**c**) The NHS England (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2022 were signed on 30th June 2022 and are available online: https://www.gov.uk/government/publications/the-nhs-england-healthcare-safety-investigation-branch-directions-2022. Hard copies are available from the Quality, Patient Safety and Maternity Team, Department of Health and Social Care, Quarry House, Quarry Hill, Leeds LS2 7UE.

(**d**) 2008 c. 14.

(**e**) Section 1 was substituted by section 1 of the Health and Social Care Act 2012 c. 7 ("the 2012 Act").

(b) the Secretary of State's duty under section 1A of the 2006 Act(**a**) 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;

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

The Maternity and Newborn Safety Investigation Programme

2.—(1) The Commission is directed to exercise the investigation functions ("the Maternity and Newborn Safety Investigation Programme") set out in this direction.

(2) The Commission must investigate each qualifying maternity case referred to it.

(3) The Commission must be open and transparent about the process that is followed in identifying qualifying maternity cases for investigation and about the processes that are to be followed in conducting an investigation.

(4) The Commission, in conducting an 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—

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

(ii) any other person as the Commission thinks appropriate, and

(f) consider how its findings compare to national guidance in relation to maternity and newborn safety.

(5) The Commission 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 Commission 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 Commission thinks appropriate,

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

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

(6) If, during the course of an investigation, the Commission identifies a serious deficiency in the practice of the provider concerned, the Commission must alert the provider to the deficiency as soon as is reasonably possible.

Exercise of functions

3.—(1) In exercising its investigation functions, the Commission must—

(**a**) Section 1A was inserted by section 2 of the 2012 Act.
(**b**) Section 2 was substituted by paragraph 10 of Schedule 5 to the 2022 Act.

(a) encourage the development of skills used to investigate local maternity and newborn safety incidents in the health service and to learn from them, including suggesting standards which may be adopted in the conduct of such investigations,

(b) produce reports in accordance with directions 4 to 6.

(2) In exercising its functions, the Commission may—

(a) do anything it considers necessary to escalate safety concerns to persons it considers appropriate, including providers (including making recommendations in reports produced pursuant to direction 4(1)),

(b) support the health service with the improvement of patient safety in maternity and newborn services, including but not limited to, participating in relevant groups or schemes with providers or other health service bodies.

Reports

4.—(1) The Commission must, within a reasonable period of time, produce a report on the matters set out in direction 2(4) and, where reasonably practicable, within 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 Commission 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, such person or persons as appear to the Commission 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 Commission thinks appropriate;

(c) the providers concerned;

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

(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 Commission considers reasonable to comment on the accuracy of, and conclusions reached in, the report.

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

(5) On completing the report, the Commission must provide a copy of that report to any person to whom a copy of the draft report has been provided pursuant to paragraph (2).

(6) The Commission may provide a copy of the report to any members of the mother or baby's family as the Commission thinks appropriate.

Further conclusions arising from the investigation

5. At the end of each investigation the Commission must—

(a) consider whether any of the conclusions drawn from the facts of the case, including recommendations from the report, or the contributing factors indicate any deficiencies in practice that should be rectified by the provider concerned or more widely ("further conclusions");

(b) disseminate any further conclusions to the providers concerned, to any other providers, or to any relevant national bodies or groups responsible for healthcare in England, who, in the Commission's view, may benefit from knowing the conclusions;

(c) alert the integrated care board, groups concerned or NHS England (as the Commission considers appropriate) to any conclusions reached 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 the Commission 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, group or other body in accordance with sub-paragraph (b) or (c).

Publication of thematic report

6.—(1) The Commission must publish a report on the investigations carried out by the Commission 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;

(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 Commission no later than 31st July 2024 and subsequent reports must be published each financial year.

(4) The Commission may produce further publications at any time on the matters set out in paragraph (2) for the purposes of securing continuous improvement in the quality of services provided as part of the health service.

Independence and transparency

7.—(1) The Commission must take reasonable steps to protect the independence of the investigations conducted under the Maternity and Newborn Safety Investigation Programme.

(2) The Commission must be open and transparent about the use of information obtained for the purpose of the Maternity and Newborn Safety Investigation Programme, including how any information may be used for other activities, such as regulatory activities, of the Commission.

Revocation and saving provision

8.—(1) Subject to paragraph (2), the 2022 Directions are revoked.

(2) Notwithstanding the revocation in paragraph (1), directions 4 to 6 of the 2022 Directions shall continue to apply in respect of ongoing investigations continued pursuant to direction 9.

Transitional arrangements

9.—(1) The Commission is directed to continue any ongoing investigations—

(a) referred to NHS England pursuant to the 2022 Directions, in accordance with directions 4 to 6 of those directions; and

(b) referred to the Trust Development Authority pursuant to the 2018 Directions and continued by NHS England, in accordance with directions 3 to 5 of those directions.

(2) For the purpose of investigations continued under paragraph (1), references to "HSIB" in the 2018 Directions and the 2022 Directions are to be read as references to the Commission.

(3) The Commission may take such actions ancillary to the duty in paragraph (1) as it considers reasonably necessary.

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

Date: 21/09/2023

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

SCHEDULE

Direction 1(2)

Criteria of qualifying maternity cases

Qualifying maternity cases

1. A qualifying maternity case is a case —

(a) which involves a baby which falls within one of the categories of "eligible babies" described in paragraph 2, or

(b) of direct or indirect maternal death set out in paragraph 3.

Eligible babies

2.—(1) Subject to sub-paragraph (2), for the purpose of paragraph 1(a) above, "eligible babies" includes all term babies (at least 37 completed weeks of gestation) born following labour who have one of the following outcomes—

(a) Intrapartum stillbirth: when the baby was thought to be alive at the start of labour but was born with no signs of life, excluding macerated stillbirths confirmed by a post-mortem.

(b) Early neonatal death: when the baby died within the first week of life (i.e. days 0–6) of any cause.

(c) Severe brain injury: diagnosed as occurring in the first 7 days of life, when the baby—

(i) was therapeutically cooled (active cooling only), or

(ii) has been diagnosed with moderate to severe encephalopathy, consisting of altered state of consciousness (lethargy, stupor or coma) and at least one of the following:

(aa) hypotonia;

(bb) abnormal reflexes including oculomotor or pupillary abnormalities;

(cc) absent or weak suck;

(dd) clinical seizures.

(2) A baby with outcomes in paragraph (1)(a) to (c) that are the result of a congenital or genetic anomaly, which is known at the point of referral of the case is not an "eligible baby" for the purpose of the definition of a "qualifying maternity case" in paragraph 1 above.

(3) For the purpose of this paragraph—

"labour" includes—

(i) any labour diagnosed by a health professional; this includes the latent phase of labour (less than 4cm dilatation);

(ii) where there has been a report to the unit of any concerns of being in labour, for example (but not limited to) abdominal pains, contractions or suspected ruptured membranes;

(iii) induction of labour;

(iv) where the baby was thought to be alive following suspected or confirmed premature rupture of membranes.

"severe brain injury" means a brain magnetic resonance imaging scan showing hypoxic damage (a type of brain injury that occurs when there is a disruption in supply of oxygen to the brain) or the baby demonstrating ongoing neurological signs or symptoms.

Maternal deaths

3.—(1) A case of a maternal death for the purposes of paragraph 1(b) means the direct or indirect death of a woman while pregnant or within 42 days of the end of the pregnancy from any

cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.

(2) For the purposes of sub-paragraph (1)—

"direct death" means deaths resulting from obstetric complications of the pregnant state (pregnancy, labour and puerperium) from—

(i) interventions,

(ii) omissions,

(iii) incorrect treatment, or

(iv) a chain of events resulting from any of sub-paragraphs (i)-(iii).

"indirect death" means deaths resulting from previous existing disease, or disease that developed during pregnancy and which was not the result of direct obstetric causes, but which was aggravated by the physiological effects of pregnancy.

"end of the pregnancy" includes giving birth, treatment of an ectopic pregnancy, miscarriage or termination of pregnancy.