The NHS England (Healthcare Safety Investigation Branch) 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) 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 2016 Directions" means the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016(**b**);

"annual allocation" means the amount of money allocated and paid by the Secretary of State to NHS England to fund the activities of the Investigation Branch for a given financial year;

"the Chief Investigator" means the person holding that appointment pursuant to direction 4(1)(a);

"commissioner" means an integrated care board(**c**), or NHS England when carrying out its commissioning functions(**d**), or a local authority exercising functions pursuant to the 2006 Act in relation to the health service(**e**);

"health service regulator" means the Care Quality Commission(**f**) or NHS England when carrying out its regulatory functions;

"the Investigation Branch" means the Healthcare Safety Investigation Branch established under direction 3(1);

"patient" means users of services provided as part of the health service in England;

"professional regulatory body" means a regulatory body within the meaning of section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(**g**);

"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.

(**a**) 2006 (c. 41). Section 7C was inserted by section 44 of the Health and Care Act 2022 (c. 31).
(**b**) These directions are revoked (see direction 12) as result of the abolition of the National Health Service Trust Development Authority by section 36 of the Health and Care Act 2022.
(**c**) Integrated care boards replaced clinical commissioning groups and were established under Chapter A3 of the 2006 Act, inserted by section 19 of the Health and Care Act 2022.
(**d**) 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 now 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.
(**e**) "The health service" is defined in section 275(1) of the National Health Service Act 2006 (the 2006 Act) to mean, in relation to England, the health service continued under section 1(1) of the 2006 Act.
(**f**) The Care Quality Commission was established under section 1 of the Health and Social Care Act 2008 (c. 14).
(**g**) 2002 (c. 17).

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.

The Healthcare Safety Investigation Branch

3.—(1) NHS England must establish a division of NHS England to be known as the Healthcare Safety Investigation Branch ("the Investigation Branch") on 1st July 2022, and provide for its operation, 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 direction in paragraph (1) includes furnishing the Investigation Branch with suitable premises, including building facilities, services, and providing the Chief Investigator with administrative support and facilities.

(3) The Investigation Branch must—

(a) continue any investigations undertaken by the National Health Service Trust Development Authority pursuant to the 2016 Directions, in line with directions 5 to 8;

(b) impose such requirements on the Chief Investigator in particular and the Investigation Branch generally, as the case may be, as are set out in those directions;

(c) permit the Chief Investigator and the Investigation Branch to take such actions ancillary to those requirements as the Chief Investigator considers reasonably necessary.

Composition of the Investigation Branch

4.—(1) The Investigation Branch must include—

(a) a Chief Investigator who, unless they transferred across from the NHS Trust Development Authority Healthcare Safety Investigation Branch(**a**), is to be appointed by NHS England subject to the approval of the Secretary of State. The Chief Investigator post can be on a fixed term or a permanent basis and they may only be dismissed with the approval of the Secretary of State; and

(b) an investigation team who, unless transferred across from the NHS Trust Development Authority Healthcare Safety Investigation Branch(**b**), is to be appointed by NHS England, subject to the approval of the Chief Investigator.

(2) The Chief Investigator and investigation team must—

(a) have the skills necessary to carry out investigations, or tasks necessary for the conduct of investigations, described in direction 5; and

(**a**) By virtue of a transfer scheme pursuant to section 38 of the Health and Care Act 2022 (c. 31).

(**b**) See above.

(b) be provided with appropriate training from time to time to enable them to carry out such investigations or tasks, and in particular to enable them to maintain and develop the skills and expertise required for their work.

(3) The Investigation Branch may, at the discretion of the Chief Investigator, consult and pay from the annual allocation the professional fees of specialists on matters requiring expertise in particular fields (such as clinical practice or healthcare technology).

Investigatory functions

5.—(1) NHS England must ensure that the Investigation Branch exercises the following functions—

(a) the investigation of incidents or accidents which, in the view of the Chief Investigator, evidence, or are likely to evidence, risks affecting patient safety;

(b) the ascertaining of facts relevant to such risks and analysis of those facts;

(c) the identification of improvements or areas for improvement, if any, which may be made in patient safety in—

(i) the provision of services as part of the health service, or

(ii) the conduct of other functions carried out for purposes of the health service, and where appropriate, the making of recommendations in relation to such improvements;

(d) the publication of reports as provided for in direction 8;

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

(2) For the purposes of paragraph (1)(a), risks affecting patient safety include, but are not limited to—

(a) risks resulting in repeated, preventable or common occurrences of safety risks or harm to patients;

(b) risks indicating a systemic problem with significant impact in more than one setting; or

(c) risks involving new or novel forms of harm or new or novel risks of harm.

(3) It is not the function of the Investigation Branch to identify civil or criminal liability in any matter, nor to apportion blame or otherwise support fault-based legal or regulatory or other formal action against persons whose actions come under consideration as part of its investigations.

(4) In identifying incidents or accidents for investigation, the Chief Investigator must have regard to—

(a) paragraph (3);

(b) the need to provide findings, analysis and, where appropriate, make recommendations that are relevant for improving current practice and systems in the health service in so far as they relate to or affect patient safety.

(5) The Chief Investigator must be open and transparent about the processes that will be followed in identifying incidents or accidents for investigation and in conducting an investigation (see directions 7 and 8).

Safe Space

6.—(1) In this direction, "safe space principle" refers to the principle that, in the view of the Secretary of State—

(a) the Investigation Branch's function of providing findings, analysis and, where appropriate, recommendations pursuant to direction 5, is best informed by comprehensive and candid contributions from those whose actions come under consideration in the course of an investigation, bearing in mind the provisions in direction 5(3) and (4)(b);

(b) contributions that are comprehensive and candid are more likely to be made where they may be made in the confidence that they will be used not for purposes of apportioning blame or establishing liability but for purposes of identifying improvements or areas for improvement, if any, which may be made in patient safety in the provision of services as part of the health service or the conduct of other functions for purposes of the health service, and making recommendations in relation to such improvements; and

(c) unless there is an overriding public interest or legal compulsion, disclosures for purposes other than making recommendations as described in paragraph (1)(b) of material gathered by the Investigation Branch should accordingly be avoided so as to preserve the confidence in the Investigation Branch's investigatory and reporting process of those whose contributions may be relied on for the purposes of current and future investigations.

(2) In conducting any investigation, the Investigation Branch—

(a) must, in respect of the following individuals or bodies as may be concerned in an incident or accident, seek to provide them with opportunities to contribute to any investigation into that incident or accident—
(i) patients and, where appropriate, family members or representatives,
(ii) providers and individuals, such as staff, within such bodies,
(iii) commissioners and individuals, such as staff, within such bodies,
(iv) health service regulators and individuals, such as staff, within such bodies;

(b) may seek contributions from such other individuals or bodies as the Chief Investigator or the investigation team consider appropriate;

(c) must facilitate and support comprehensive and candid contributions from those whose actions come under consideration in the course of an investigation in respect of how an incident or accident arose;

(d) must seek to encourage sharing of information about incidents and accidents between persons mentioned in paragraph (2)(c) on the one hand, and on the other, the patient whose care is under consideration in the course of an investigation and, where appropriate, that patient's family or representative.

(3) In holding and processing any information and other material the Investigation Branch gathers in the course of an investigation, the Investigation Branch must act in a manner that is consistent with its functions bearing in mind in particular direction 5(3) and (4)(b) and the safe space principle.

(4) The Chief Investigator—

(a) must approve all decisions about the disclosure of any material gathered by the Investigation Branch outside of the Investigation Branch;

(b) may, when requested to do so, disclose to the patient, or where appropriate, to the patient's family or representative, material gathered by the Investigation Branch in the course of an investigation in which that patient's care is under consideration, but such disclosure may only be made of such information, in such form (anonymised or otherwise) and to such extent that the Chief Investigator judges, in the individual circumstances of the request, to be consistent with the safe space principle;

(c) must inform the appropriate health service regulator, professional regulatory body or other investigatory body or bodies should the Investigation Branch become aware of evidence of a serious, continuing risk to patient safety, but subject to this sub-paragraph must not volunteer to take further part in the actions that such a body or bodies may subsequently take;

(d) must seek to agree with professional regulatory bodies and other investigatory bodies which have statutory powers to require information, suitable protocols respecting the safe space principle in relation to the exercise of those statutory powers;

(e) must seek to agree with the Care Quality Commission, National Institute for Health and Care Excellence, the Health and Social Care Information Centre, and Special Health Authorities which have functions that are exercisable in relation to England, suitable protocols respecting the safe space principle which are to apply as between those bodies and NHS England, should they co-operate with each other in the exercise of their respective functions;

(f) must, in considering the application of the provisions of the Freedom of Information Act 2000(**a**) in response to such requests that may be made under that Act, have in mind the safe space principle;

(g) must (so far as permissible within the relevant procedural rules) make representations in respect of the safe space principle to a court or tribunal which is considering whether to require the disclosure of material gathered by the Investigation Branch in the course of conducting its investigations or functions preliminary to such investigations;

(h) must provide information when required by a Court Order or as a matter of statutory requirement, but except as provided for in sub-paragraph (b), in the absence of an overriding public interest, must otherwise seek to avoid voluntary disclosures of material gathered by the Investigation Branch.

(5) Notwithstanding the provisions of paragraphs (2) to (4), the Chief Investigator and the Investigation Branch may include in a report or an interim report that is produced pursuant to direction 8(2) or (3) such material that the Chief Investigator considers reasonably necessary to include for the purposes of discharging the functions in directions 5 and 8.

(6) For the avoidance of doubt, nothing in this paragraph requires the Chief Investigator or the Investigation Branch to act in breach of the Data Protection Act 1998(**b**).

(7) In direction 6, for the purposes of sub-paragraphs (2)(a)(i) and (d) and (4)(b), subject to any lawful requirement to the contrary, the Chief Investigator has discretion to decide about the appropriateness of involving members of the family of a patient, or a patient's representative in an investigation, but so far as is reasonable must seek to reflect the wishes of the patient and the patient's representative, and for the purposes of that direction—

(a) "representative" refers to any person who lawfully speaks and makes decisions in connection with the matters in question on behalf of the patient concerned, and whose interest in that capacity has been made known to the Investigation Branch; and

(b) "investigatory body" includes the Health and Safety Executive, the police and the Crown Prosecution Service.

Investigation Principles

7.—(1) NHS England must ensure that the Chief Investigator develops and publishes a document setting out the principles, consistent with these Directions, that are to govern investigations carried out by the Investigation Branch ("the Investigation Principles").

(2) The Investigation Principles must set out, in particular—

(a) the nature of the events, circumstances, or outcomes that will be relevant factors in the Chief Investigator's decision as to the incidents or accidents which will be investigated, bearing in mind the matters mentioned in direction 5(4);

(b) the period of time in which the Investigation Branch will generally seek to conclude investigations, and factors that may lead to the period being extended;

(**a**) 2000 (c. 36).
(**b**) 1998 (c. 29).

(c) the range of procedures and investigation methods which the Investigation Branch may use in conducting an investigation.

(3) The Chief Investigator may review the published Investigation Principles and update those Principles, if appropriate, in light of that review, at any time and in any event must do so at least once in each financial year.

Investigation Process and Reports

8.—(1) Before the Investigation Branch begins an investigation, the Chief Investigator must publish the timetable and procedures envisaged for that investigation.

(2) At the end of any investigation the Chief Investigator must publish a report of that investigation which—

(a) summarises the methodology used to carry out the investigation;

(b) presents findings of fact made as a result of the investigation and an analysis of those factual findings so far as consistent with the matters set out in direction 5(1)(a) to (c), (3) and (4)(b);

(c) makes any recommendations that the Investigation Branch considers appropriate for the purposes of the functions described in direction 5;

(d) focuses on risks affecting patient safety as referred to in direction 5(1)(a) and the making of recommendations, if appropriate, in accordance with direction 5(1)(c) that address such risks, rather than focus on the activities of particular individuals;

(e) does not include the name of any individual or any personal details that could make them easily identifiable, unless permission to do so has been given by the individual;

(f) is of such length and in such detail as the Chief Investigator considers warranted in light of the nature and severity of the incident or accident the subject of the report.

(3) The Chief Investigator may publish an interim report meeting the requirements of sub-paragraphs (2)(a) to (f) which contains interim findings and analysis and, if appropriate, provisional recommendations, on any matter in respect of which the Chief Investigator considers—

(a) there is sufficient certainty of a risk of harm to patients to warrant urgent publication; and

(b) that risk is likely to be reduced if knowledge of those interim findings or provisional recommendations is disseminated to the public.

Maintaining the independence of the Investigation Branch

9.—(1) NHS England must, in establishing and maintaining the Investigation Branch, take reasonable steps to protect the independence of the Investigation Branch from the other activities of NHS England.

(2) NHS England must take reasonable steps to prevent other persons from doing anything to undermine the independence of the Investigation Branch.

(3) NHS England must establish a group of independent advisors ("the advisory group") whose role is to meet with the Chief Investigator from time to time to discuss with the Chief Investigator the following matters—

(a) the independence of the reports published by the Investigation Branch pursuant to direction 8(2) and (3);

(b) the independence of the Investigation Branch in relation to the other activities of NHS England;

(c) the independence of the Investigation Branch in relation to persons other than NHS England.

(4) NHS England may appoint such number of advisors to the advisory group as it and the Chief Investigator may agree, and each appointment must be made subject to the approval of the Chief Investigator.

(5) NHS England must require the advisory group to report to the Chief Investigator, at such intervals as the Chief Investigator stipulates, with its observations in respect of the matters set out in sub-paragraph (3).

(6) The travelling and other agreed out-of-pocket expenses of members of the advisory group must be paid from the annual allocation.

Annual Reporting obligations and Accountability

10.—(1) The Chief Investigator must report—

(a) to NHS England in relation to budgetary matters including the spending, staffing levels and staffing needs and administrative efficiency of the Investigation Branch;

(b) to the Secretary of State in relation to the performance of functions by the Investigation Branch.

(2) At the beginning of each financial year, the Chief Investigator must prepare and provide to the Secretary of State an annual report of the Investigation Branch's activities for the preceding financial year, subject to paragraph (3).

(3) The annual report produced in 2023—

(a) must report on the Investigation Branch's activities in the period beginning on the 1st July 2022, and ending on the 31st March 2023; but

(b) may also report on the activities of the Investigation Branch, established pursuant to the 2016 Directions, in the period beginning on the 1st April 2022, and ending on the 30th June 2022.

(3) NHS England must ensure that each annual report is published after it has been provided to the Secretary of State. Publication may be online, but a paper copy must be provided free of charge to any person who requests it in writing(**a**).

(4) The Chief Investigator must expect to be called to give evidence to Parliament, in particular to the Health Select Committee and the Public Administration and Constitutional Affairs Committee, about the activities of the Investigation Branch and related matters.

Funding

11.—(1) The Chief Investigator must, before the beginning of the financial year, provide to NHS England and publish a budget assessment in relation to that financial year.

(2) NHS England must provide a copy of the budget assessment to the Secretary of State.

(3) NHS England must ensure that in each financial year, it pays to the Investigation Branch the entirety of the annual allocation and any extraordinary payment.

(4) In the event that the Secretary of State makes an extraordinary payment, NHS England and the Investigation Branch must ensure it is spent only on the investigation for which the payment is made.

(**a**) Requests may be made to NHS England, London, Skipton House, 80 London Road, London, SE1 6LH.

(5) In the event of any surplus arising, NHS England must seek instructions from the Secretary of State as to its disposal at the end of the financial year, or, in the case of a surplus arising from an extraordinary payment, at the end of the investigation in respect of which the payment was made.

(6) In this direction—

"budget assessment" means the Chief Investigator's assessment of the cost of the resources that will be required for the operation of the Investigation Branch over the course of a financial year;

"extraordinary payment" means a payment made to NHS England by the Secretary of State, in addition to the annual allocation, to fund a specific investigation by the Investigation Branch;

"surplus" means any sum of money from the annual allocation which remains unspent by the Investigation Branch at the end of the financial year or, as the case may be, any sum of money from an extraordinary payment which remains unspent by the Investigation Branch at the end of the investigation in respect of which the payment was made.

Revocations

12. The following directions(**a**) are revoked—

(a) The Consolidated Provider Accounts Directions 2018;

(b) The National Health Service Trust Development Authority Directions and Revocations and the Revocation of the Imperial College Healthcare National Health Service Trust Directions 2016;

(c) The 2016 Directions;

(d) The NHS Trust Development Authority (HSIB) (additional investigatory functions in respect of maternity cases) Directions 2018;

(e) The National Health Service Trust Development Authority (Leadership Academy) Directions 2019.

Signed by authority of the Secretary of State

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

Date: 30th June 2022

(**a**) A hard copy of all the Directions listed in direction 12 can be obtained from the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU.