



Department
of Health &
Social Care



Memorandum of Understanding
between
the Department of Health and Social Care and
the Healthcare Safety Investigations Branch

2017/18

MoU between DHSC and the HSIB

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1. Preamble

- 1.1. This Memorandum of Understanding has been drawn up by the Department of Health and Social Care in consultation with the Healthcare Safety Investigation Branch (HSIB) (a branch of NHS Improvement).
- 1.2. This document sets out the relationship between the Department of Health and Social Care and the HSIB and their respective responsibilities within that relationship.
- 1.3. This document also takes into account agreements, including accountability arrangements, between the HSIB and its host organisation, the NHS Trust Development Authority, and should be understood within the context of those agreements, and the dual accountability mechanisms set out in the Secretary of State Directions to the NHS Trust Development Authority, 2016, by which the HSIB was established.¹
- 1.4. The document does not convey any legal powers or responsibilities. It is signed and dated by the Department and the HSIB.

2. Purpose of this document

- 2.1. This document is intended to set out an agreed way of working between the Department of Health and Social Care (DHSC) and the Healthcare Safety Investigation Branch (HSIB), in relation to the operation of the HSIB.
- 2.2. This document sets out how this relationship will operate on a day to day basis, to support the independent delivery of HSIB's functions and enable proper accountability for its work.
- 2.3. This document sets out the principles governing the relationship between DHSC and HSIB, and gives an agreement between the two organisations to work together in a way that is cooperative and respectful of the separate roles and responsibilities of each organisation.
- 2.4. This is the first Memorandum of Understanding between the Department and HSIB. HSIB is a newly formed organisation in its first full year of operation. As such, this document will be kept under review (see paragraph 10).

3. The Healthcare Safety Investigations Branch

Purpose and Functions

- 3.1. The HSIB has been established to undertake investigations into any incident or accident which has posed a risk to patient safety, with a particular emphasis on establishing the facts of the case, and identifying lessons for the whole system, where patient safety can be improved. The HSIB has a further role to exemplify and define, for the NHS, excellent, high quality healthcare

¹ The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 are available at: <https://www.gov.uk/government/publications/nhs-trust-development-authority-directions-2016>.

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safety investigations and good practice in carrying out such investigations. Finally, the HSIB has a role in supporting the local NHS to develop the skills and culture to enable it to better investigate and learn from healthcare safety incidents.

- 3.2. It is not the purpose of the HSIB to identify civil or criminal liability in any matter or to apportion blame.
- 3.3. The HSIB was established through Secretary of State Directions as a division of the NHS Trust Development Authority, which operates with Monitor as NHS Improvement. The Directions specify HSIB's functions which HSIB is intended to undertake in a way that is operationally independent from its host organisation. Separate Secretary of State Directions to the NHS Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) 2018 set out the functions and principles relevant to the specific set of maternity investigations that the HSIB will undertake (this set is defined further at 3.4(ii) below.)
- 3.4. Those functions are:
 - i. (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—
 - the provision of services as part of the health service, or
 - the conduct of other functions carried out for purposes of the health service; and
 - the making of recommendations, where appropriate, in relation to such improvements;
(d) the publication of investigation reports;
(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.
 - ii. (a) the investigation of all qualifying maternity cases beginning in one region from April 2018 and rolling out to all regions in England by April 2019, and continuing in all regions thereafter. A qualifying case is:
 - a case, as described in the 2015 Each Baby Counts Report², which involves a baby which falls within one of the categories of "eligible babies"³; or

² Each Baby Counts Report 2015, Royal College of Obstetricians and Gynaecologists, London: RCOG, 2017. Available online at: <https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/each-baby-counts/ebc-2015-report/>.

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- a case of direct or indirect maternal death as defined in the MBRRACE-UK report, *Saving Lives, Improving Mothers' Care* dated December 2016⁴;

(b) The production of reports of completed investigations, including recommendations for relevant NHS providers and commissioners, as appropriate, for each maternity case described in 3.4(ii)(a) within a reasonable period of time, not to exceed six months from the date of referral of the qualifying maternity case.

(c) The publication of an annual report drawing together the overarching themes and points of learning from the maternity investigations, and where appropriate, making recommendations for the purposes of securing continuous improvement in the quality of services provided as part of the health service.

- 3.5. The HSIB is required to report to the Secretary of State for Health and Social Care on the performance of its functions.

Governance

- 3.6. The HSIB is formally established as a division of the NHS Trust Development Authority. Under the Directions establishing the HSIB, the HSIB is intended to undertake its functions and duties in a way that is operationally independent from its host organisation.
- 3.7. The Chief Investigator of HSIB is formally appointed as an employee of the NHS Trust Development Authority, but this appointment can only be made with the approval of the Secretary of State for Health and Social Care. Administrative support for this appointment will be provided by the Department of Health and Social Care. The appointment is subject to a pre-appointment hearing of the Public Administration and Constitutional Affairs Select Committee (PACAC).
- 3.8. The Chief Investigator reports to the Secretary of State on the performance of his functions, and can only be removed from his post by the Secretary of State.
- 3.9. The Chief Investigator has the power to appoint all other members of staff to the HSIB, and is responsible for the work of the whole Branch.

³ “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.

⁴ Knight M, Nair M, Tuffnell D, Kenyon S, Shakespeare J, Brocklehurst 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: p.9. Available online at: <https://www.npeu.ox.ac.uk/downloads/files/mbrance-uk/reports/MBRRACE-UK%20Maternal%20Report%202016%20-%20website.pdf>

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- 3.10. The Chief Investigator is also required to recruit and support a panel of independent advisors whose role will be to take an overview of the HSIB's activities and report on the independent operation of these activities to the HSIB.

Funding

- 3.11. NHS Trust Development Authority as part of NHS Improvement has a formal role in hosting HSIB as an operationally independent branch of NHS Improvement. As part of this role, the NHS Trust Development Authority will provide HSIB with funding that is allocated to the HSIB by the Secretary of State for Health and Social Care.

4. Accountability

- 4.1. The HSIB has dual lines of accountability:
- on financial and budgetary matters, to NHS Improvement and its Chief Executive
 - on performance of its functions, to the Secretary of State for Health and Social Care.

Financial accountability

- 4.2. The HSIB is accountable for financial and budgetary matters to its host organisation, the NHS Trust Development Authority, which, together with Monitor, operates as NHS Improvement.
- 4.3. The HSIB is required by Secretary of State Directions to report to NHS Improvement in relation to budgetary matters including the spending, staffing levels and staffing needs. The HSIB agrees to make quarterly budget reports to NHS Improvement. As the Secretary of State also has an interest in the funding and operation of the HSIB, the HSIB agrees to make these reports available to the Secretary of State through the Department of Health and Social Care.
- 4.4. To support the Secretary of State in the allocation of funds for HSIB, HSIB is required to publish a budget statement before the start of each financial year, setting out information relating to its plans and budget for the upcoming financial year. HSIB agrees to provide this budget statement to the NHS TDA and via this route, to the Secretary of State in line with the provisions set out in the Directions.
- 4.5. Full details of these financial accountability arrangements, based on the 2016 Directions, are set out in a Memorandum of Understanding agreed between the HSIB and NHS Improvement.

Performance accountability

- 4.6. The HSIB is accountable to the Secretary of State for Health and Social Care in relation to the performance of its functions, as set out in the 2016 Secretary of State Directions by which it was established.

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- 4.7. The HSIB will attend quarterly accountability review (QAR) meetings with the Department of Health and Social Care and NHS Improvement. These meetings will:
- review the performance of the HSIB against the HSIB's objectives, functions and duties as set out in the 2016 Secretary of State Directions, and with reference to a set of agreed key performance indicators set out at Annex A of this document.
 - review the HSIB's business planning, in relation to its delivery of its objectives, functions and duties
 - discuss any budgetary or financial issues that may impact on delivery of the HSIB's objectives, functions and duties
 - ensure there is an open, transparent, joined up working relationship and a culture of constructive challenge, co-operation and collaboration between the Department of Health and Social Care and the HSIB;
 - resolve any other outstanding issues, including issues regarding the performance of the HSIB, the working relationship between the Department and the HSIB, or the relationship between the HSIB and other bodies in the health and care system; and
 - allow opportunity for the Department of Health and Social Care to provide an update to the HSIB on recent developments.
- 4.8. QAR meetings will be governed by terms of reference agreed between DHSC and HSIB.
- 4.9. At the beginning of each financial year, the Chief Investigator will provide the Secretary of State for Health and Social Care with an annual report of the HSIB's activities over the previous year. The HSIB agrees to produce this annual report as soon as possible after the end of each financial year, publish it online and make it available in hard copy when requested.
- 4.10. Key performance indicators relating to HSIB's functions and to be used in assessing HSIB's performance will be agreed between DHSC and HSIB and reviewed on an annual basis.
- 4.11. The DHSC also reserves the right to raise financial matters insofar as they relate to HSIB's performance.

Parliamentary accountability

- 4.12. The Secretary of State is accountable to Parliament for the health system, including the HSIB. The Department of Health and Social Care supports the Secretary of State in this role. This involves:
- accounting to Parliament for the HSIB's performance and the effectiveness of the health and care system overall; and
 - supporting the integrity of the system by ensuring that funding, legislation and accountability arrangements protect the best interests of patients, the public and the taxpayer.

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- 4.13. Accountability to Parliament will often be demonstrated through parliamentary questions, MPs' letters and appearances before parliamentary committees. Where the Secretary of State needs to demonstrate accountability to Parliament, the HSIB will provide assistance and information to the Department to support this.
- 4.14. The HSIB will, for example, assist the Department in responding to any parliamentary questions, debates or other parliamentary activities that relate to the work of HSIB by providing timely briefing on the issues raised. Such briefings will be managed for the Department through the HSIB sponsor branch. Any information provided by the HSIB will be timely, accurate and, where appropriate, consistent with information provided by the Department.
- 4.15. To facilitate this, the Department and the HSIB/NHS Improvement have agreed a public and parliamentary accountability protocol that sets out how they will work together to secure the confidence of the public and Parliament, and to maintain the service levels that MPs and the public have come to expect.
- 4.16. The HSIB has its own lines of accountability to Parliament. As set out in the 2016 Directions, 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 HSIB and related matters. The Chief Investigator of the HSIB will attend Parliament to give evidence to any committees when called.

5. Sponsorship

- 5.1. Sponsorship refers to the way in which the Department of Health and Social Care relates to its arm's length bodies on behalf of the Secretary of State, and includes a set of formal mechanisms for seeking assurance on the way in which those organisations are discharging their functions.
- 5.2. The Permanent Secretary has appointed the Director of Acute Care and Quality as the Senior Departmental Sponsor (SDS) for the HSIB.
- 5.3. The SDS acts as the link at executive level between the HSIB and the senior officials of the Department, and also with ministers. Whilst the SDS role is facilitative and recognises the need for direct engagement between the HSIB and other parts of the Department and ministers, it also supports the Secretary of State in holding the HSIB to account and providing assurance on its performance.
- 5.4. The SDS will hold quarterly accountability review (QAR) meetings with the Chief Investigator of the HSIB. These meetings will be governed by terms of reference agreed between DHSC and the HSIB and will also be attended by NHS Improvement. Ministers may also attend these meetings.
- 5.5. Quarterly accountability meetings will review the HSIB's delivery of its objectives, functions and duties over the preceding quarter and are structured to promote openness and constructive challenge.
- 5.6. These meetings will also provide both the DHSC and HSIB with the opportunity of raising any upcoming issues which may be of interest to either

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body relating to the delivery of the HSIB's functions and to identify and resolve any strategic issues.

- 5.7. The DHSC and HSIB will hold any other regular or extraordinary formal meetings, relating to any aspect of HSIB performance, operational matters or accountability arrangements, as required.
- 5.8. The DHSC's Quality, Patient Safety and Investigations (QPSI) Team will be the sponsor branch for the HSIB. In that capacity, the QPSI Team will provide secretariat support to the quarterly accountability meetings and any other formal meetings and will be the day to day point of contact for the HSIB.
- 5.9. The Secretary of State will hold annual accountability review meetings of the HSIB's performance with the Chief Investigator of the HSIB.

6. Partnership Working

- 6.1. The HSIB and the Department agree that their relationship will be characterised by openness, transparency and a mutual respect and support for the independent delivery of the functions of each organisation.
- 6.2. To support the development of this relationship, the Department of Health and Social Care and the HSIB have agreed to a set of shared principles:
 - working together with each other, and with the Department's other ALBs, for patients, people who use services and the public;
 - respect for the independent operation of each organisation, and the freedom to exercise their functions in the way they consider most appropriate;
 - recognition that the Secretary of State is ultimately accountable to Parliament and the public for the system overall. The HSIB supports the Department in the discharge of its accountability duties, and the Department supports the HSIB in the same way; and
 - working together openly and positively. This will include working constructively and collaboratively with other organisations within and beyond the health and social care system.
- 6.3. To facilitate this agreed way of working, the HSIB and DHSC undertake to agree a communications protocol and to inform one another, in a timely fashion, of any work programmes, publications or media interest which is likely to be of relevance to the delivery of the other's functions. The HSIB will keep the Department informed of any issues with an impact on the development or implementation of relevant policy and legislation. Likewise, the Department will seek to keep the HSIB apprised of developments in policy, legislation and Government that affect its work, wherever appropriate. The Department and the HSIB will make clear which issues fall into this category in good time. The Department's sponsor team and the HSIB are responsible for ensuring that this works effectively.
- 6.4. In doing so, both organisations recognise the importance of the autonomy and independent operation of each organisation, and undertake not to exert undue influence on the way in which these functions are carried out.

- 6.5. In discharging its functions, the HSIB also undertakes to work co-operatively and collaboratively with other local and national bodies responsible for the health and care system in England, insofar as such cooperation does not compromise the exercise of HSIB's functions as set out in the 2016 Directions. This includes collaborative work to address national recommendations for health and care system bodies.
- 6.6. HSIB also undertakes to agree protocols with bodies with whom it regularly interacts in carrying out its functions and duties, setting out agreed ways of working. Such bodies may include, but are not limited to, arms length bodies of the Department, professional healthcare regulators and the police.

7. Information governance

- 7.1. The HSIB as a branch of the NHS Trust Development Authority will take all necessary measures to ensure that:
- patient, personal and/or sensitive information within its care and control is well managed and protected through all stages of its use, including through compliance with the Data Protection Act;
 - it provides public assurance in respect of its information governance practice by completing and publishing an annual information governance assessment using an agreed assessment mechanism; and
 - it meets its legal obligations for records management, accountability and public information.
- 7.2. NHS Trust Development Authority's Senior Information Risk Owner and Caldicott Guardian will work together with HSIB to ensure that both patient and other personal information are handled in line with best practice in government and the wider public sector.

8. Whistleblowing

- 8.1. The NHS Trust Development Authority (including the HSIB), as with the Department and all its ALBs, has whistleblowing policies and procedures in place that comply with the Public Interest Disclosure Act 1998 and best practice guidance.⁵ The Act prohibits the use of confidentiality clauses that seek to prevent staff from speaking out on issues of public interest.

9. Equalities

- 9.1. The public sector equality duty (PSED) requires the NHS Trust Development Authority (including the HSIB), to have due regard, as a public body, to the need to:
- eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under this Act;

⁵<http://www.nhsemployers.org/EmploymentPolicyAndPractice/UKEmploymentPractice/RaisingConcerns/Pages/RaisingConcerns.aspx>

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- advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it; and
 - foster good relations between persons who share a relevant protected characteristic and persons who do not share it.
- 9.2. The provisions of the Equality Act 2010 (Specific Duties) Regulations 2011 require the NHS Trust Development Authority (including the HSIB), as a public body, to:
- annually publish information to demonstrate compliance with the PSED. This information must include, in particular, information relating to persons who share a relevant protected characteristic who are its employees (provided the organisation has 150 or more employees) and other persons affected by its policies and procedures; and
 - prepare and publish one or more objectives it thinks it should achieve to meet the PSED.⁶
- 9.3. The HSIB is expected to provide the NHS Trust Development Authority with the information required to meet these obligations.

10. Review

- 10.1. This Memorandum of Understanding and the Key Performance Indicators that accompany it will be reviewed every three years, or sooner upon request of either party, to ensure that it remains current and fit for purpose. An early review after the first full year of operation may be required in light of the HSIB's status as a new organisation to ensure that it reflects developing understanding of the exercise of HSIB's functions and the impact of this on performance.

Signed on behalf of the HSIB:



Keith Conradi
Chief Investigator, Healthcare Safety Investigation Branch
Date: 18 May 2018

⁶ This was required by 6 April 2013, and is required every four years thereafter.

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Signed on behalf of the Department of Health and Social Care:

A handwritten signature in black ink, appearing to read "William Vineall".

William Vineall
Director, Acute Care and Quality, Department of Health
Date: 18 October 2017
Revised: 24 May 2018

ANNEX A - KEY PERFORMANCE INDICATORS

HEALTHCARE SAFETY INVESTIGATIONS BRANCH

Core high-level learning investigations

- a) Publication of criteria for investigations within first quarter of operation.
- b) Undertake up to 30 per year.
- c) Publish final reports for all investigations undertaken.
- d) Undertake internal audit of investigative processes.
- e) Produce annual reports.

Investigative process

- f) Demonstrate routes of referral
- g) Plan for and commence evaluation of investigation and ways of working
- h) Seek 360° feedback from those involved in investigations

Maternity investigations

- i) Complete initial implementation of maternity investigation infrastructure in the first region by April 2018.
- j) Begin maternity investigations within one region from April 2018 and in other regions as they become active during 2018/19.
- k) All maternity investigations in active regions (as described in 3.4(ii)(a) above) to be completed in a period not to exceed 6 months of referral and HSIB to provide a full explanation of any delays beyond this 6 months period.
- l) Complete rollout of investigative infrastructure to all regions by April 2019.
- m) Demonstrate readiness to undertake circa 1000 maternity investigations of all EBC notified cases and all direct or indirect maternity deaths across all regions from April 2019.
- n) Publish an annual thematic report drawing together themes and learning from maternity investigations.

Working with other health and care system organisations

- o) Agree and publish Memorandum of Understanding with NHS TDA, as host organisation.
- p) Agree and publish Memoranda of Understanding and ways of working protocols with other relevant system bodies.

Education, training and standards

- q) Produce a set of national standards for good investigative practice.
- r) Scope and develop a set of qualifications for professional investigators.
- s) Scope and pilot a regional framework model for conducting high quality investigations.