Department of Health

FACT SHEET 6

The Draft Health Service Safety Investigations Bill – the investigation process

"Most of those who complain about NHS services do not seek financial redress … they wish to have their concerns and experiences understood and for any failings to be acknowledged and put right."

Complaints and Raising Concerns, Health Committee report, 13 January 2015

This fact sheet provides a brief overview of the process of a healthcare safety investigation as expected to be conducted by the Health Service Safety Investigations Body (HSSIB).

Background

1. The Draft Health Service Safety Investigations Bill proposes a new independent healthcare investigation body to conduct investigations using 'safe space' which will focus on learning from safety incidents in the NHS to improve patient care.

2. The Health Service Safety Investigations Body (HSSIB) will investigate incidents and issues that provide the greatest potential for learning and improvement across the healthcare system.

3. The HSSIB will investigate up to 30 serious patient safety issues a year.

How will an HSSIB investigation work?

4. **Phase 1:** The HSSIB will be required to consider any request from a patient, family member, healthcare professional, group or organisation to investigate a safety concern which meets its published criteria. The HSSIB will also need to consider any requests by the Secretary of State to investigate and be alert for current incidents which meet its criteria for investigation.

5. All requests will be considered against the HSSIB's published criteria and the HSSIB will decide whether to conduct a preliminary investigation to determine if there is cause for wider concern.

6. If the HSSIB decides not to investigate further, it will inform the person or organisation which raised the concern.

7. **Phase 2:** If an investigation is to proceed, the HSSIB will inform the relevant regulatory bodies; the person or organisation who made the request; and the chief executive of the NHS trust or provider being investigated.

8. Other relevant subject matter experts may be called upon to join the investigation team, if necessary.

9. The investigation will initially focus on the service where concerns were raised. The HSSIB may then widen its scope to explore whether the concern is more widespread within the health system. This could involve scanning for national incident patterns and investigating similar cases in other locations. The HSSIB will also consider if

lessons can be learned from existing good practice elsewhere in the NHS.

10. The HSSIB will have a duty to co-operate with national healthcare bodies and regulators during the course of an investigation but will not share information it has gained unless the High Court orders it to do so.

11. However, the HSSIB can share information, documents, equipment or items with regulators or police if there are concerns of serious misconduct, an ongoing risk to patient safety or criminal activity.

12. The HSSIB may produce an interim report at any point during its investigation if swift action is necessary, or if learning can be shared prior to the final report.

13. **Phase 3:** When the investigation is completed the HSSIB will produce a draft final report for circulation amongst all participants, inviting comments.

14. A final report will then be published setting out findings of fact, conclusions and recommendations, focusing on the wider lessons for patient safety across the system. The report will also identify actions for named persons, who will be required to publish their responses within a specified deadline.

How will the HSSIB be different from other healthcare investigators?

15. We expect that the HSSIB will be able to rely upon a dedicated team of investigators with a range of backgrounds in NHS services, safety-critical systems investigations, human factors disciplines and other professional investigative expertise.

16. Investigations will be subject to the prohibition on disclosure ('safe space') allowing patients, families, NHS staff and other participants to be as candid and open as possible in the information they provide. Information gained during a 'safe space' investigation will be protected from disclosure apart from in certain limited circumstances. This is comparable to similar legal provisions for bodies that investigate air and marine accidents.

17. It is not the purpose of the HSSIB to seek to apportion blame or liability but to help improve patient safety by embedding a culture of learning across the NHS.

18. While most people and organisations are expected to cooperate with a healthcare safety investigation, the HSSIB will have legal powers to require information, and enter premises to inspect documents and interview witnesses, if necessary.

19. The HSSIB will be required to develop processes that involve patients and their families in HSSIB investigations, as far as is reasonable and practical.

Will there be any restrictions on investigations?

20. The HSSIB is expected to have agreements with professional healthcare regulators governing how the organisations will work together and enabling the same or similar investigations to be conducted alongside each other.

21. The HSSIB will not be responsible for investigating all patient safety incidents in the NHS and will not replace existing frameworks for investigating serious incidents in the NHS.

FURTHER INFORMATION

- *Investigating Clinical Incidents in the NHS,* Public Administration Select Committee, 24 March 2015 https://www.publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/886/886.pdf
- *Complaints and Raising Concerns*, Health Committee, 13 January 2015 https://www.publications.parliament.uk/pa/cm201415/cmselect/cmhealth/350/350.pdf