UK Health Security Agency

Prevention of Future Deaths Report (Regulation 28): UKHSA's response

UKHSA would like to start this response by expressing our deepest sympathies to the family of Laura Farmer.

Background

1. On 16 September 2024, UKHSA received a Prevention of Future Deaths (PFD) report from Senior Coroner Mary Hassell, Inner North London St Pancras Coroner's Court. The PFD report was issued after an inquest into the death of Mrs Laura Farmer. UKHSA had not been invited to provide evidence at the inquest, nor were UKHSA officials notified that an inquest was taking place. UKHSA was therefore unable to provide important information to assist the Senior Coroner in preparing her findings. UKHSA's response sets out details which it considers relevant, including its investigations concerning Laura Farmer, to provide the Senior Coroner with a full picture. The response also addresses concerns raised by the Senior Coroner in the PFD report.

UKHSA's role in outbreak management

2. UKHSA's primary objective in outbreak management is to protect public health: by identifying the source and cause of infection and transmission dynamics, and by implementing control measures to prevent further spread or recurrence. It is not within UKHSA's remit to investigate the death of an individual. The roles of UKHSA and key external stakeholders in outbreak management, including the Food Standards Agency (FSA), the Medicines and Healthcare Products Regulatory Agency (MHRA), local government and NHS England are complementary. In practice these organisations work closely as part of a single public health system to deliver effective protection for the population from health threats. The regional UKHSA team (also known as health protection team, HPT) will investigate the public health outbreak/hazard (as opposed to individual deaths), help identify the source and provide local health protection services, expertise, response and advice to partners. UKHSA has a coordination and advisory role primarily, supporting for example, the FSA, MHRA and NHS England in leading their own investigations.

Shiga toxin producing Escherichia coli (STEC)

3. STEC, also known as Vero cytotoxin-producing Escherichia coli (VTEC), are bacteria that can cause gastroenteritis. Symptoms vary from mild to bloody diarrhoea and, in severe cases, can cause haemolytic uraemic syndrome (HUS), a serious and life-threatening condition predominantly affecting the kidneys. A small proportion of patients, mainly children, develop haemolytic uraemic syndrome (HUS) (1).

4. The main reservoir for STEC is cattle although it is also carried by other ruminants such as sheep, goats and deer. Transmission can occur through direct or indirect contact with animals or their environments, consumption of contaminated food or water, and person-to-person spread. STEC infections can present as sporadic cases or as outbreaks. Recent outbreaks have been

associated with beef products, cucumber, watermelon, watercress, salad leaves, unpasteurised cheese and ready to eat sandwiches.

5. Household transmission can occur, but it is rare to observe household transmission outside of those with children under the age of five or those who are unable to maintain adequate personal hygiene.

Investigation of cases and clusters of STEC

6. Diagnostic laboratories are required to notify UKHSA once identification of STEC has been made, in accordance with The Health Protection (Notification) Regulations 2010. Similarly, cases where there is a clinical suspicion of HUS, regardless of whether there is microbiological evidence of an infectious cause, should be notified to the Proper Officer of the local authority to allow prompt investigation and action. In most cases, local authorities appoint a consultant in communicable disease/health protection based within UKHSA regional teams as their Proper Officers.

7. All STEC cases are investigated as per UKHSA's Operational Guidance for STEC (Shiga toxin-producing Escherichia coli: public health management - GOV.UK (www.gov.uk). The aim of the public health investigation of individual cases is to prevent onward transmission and to gather risk factor information to identify and control sources of infection.

8. On notification UKHSA arranges for an enhanced surveillance questionnaire (ESQ) to be completed to obtain a detailed history of exposures seven days prior to onset of illness. The ESQ collects demographic details, risk status, clinical conditions and exposures including travel, food and water consumption, environmental exposures, contact with animals and outbreak status. The full questionnaire is available at: Shiga toxin-producing Escherichia coli: questionnaire - GOV.UK (www.gov.uk).

9. In cases where there are people in the household aged five and under, or those who are unable to perform adequate personal hygiene or who work in high-risk settings (for instance handling food or working with young children) UKHSA or the local authority team may recommend additional testing or exclusion from work or childcare.

10. For the vast majority of single cases, it is not possible to identify a specific source of infection despite thorough investigation.

11. UKHSA works in partnership with local authority environmental health teams and other relevant agencies (for instance the FSA) to undertake these investigations.

12. Completed ESQs are reviewed by UKHSA regional teams and used to inform action. They are also submitted to the national Gastrointestinal Infections, Food Safety and One Health (GIFSOH) Division within UKHSA to be included in the national enhanced surveillance system for STEC (NESSS), which combines microbiological, clinical and exposure information and is routinely used to check for links between cases.

13. All samples which are positive for STEC at frontline diagnostic laboratories are referred for confirmation and typing using whole genome sequencing (WGS) at the national reference laboratory.

14. Routine analysis of WGS data by the GIFSOH team is used to identify genomic clusters, defined as two or more cases with the same STEC strain.

15. Overall, around 1500 cases of STEC are reported in England every year, with between 250 and 450 clusters detected, the majority of which (~80%) are small at five cases or less. UKHSA's Operational Guidance for STEC is followed when assessing these clusters. Despite thorough multi-agency investigations, for foodborne outbreaks it is not always possible to identify the vehicle of infection or confirm the source of contamination. In 2021, of the four national investigations into foodborne STEC outbreaks, suspected vehicles were identified in two (pasta pots and watermelons) and it was not possible to identify a vehicle for the other two: (https://www.gov.uk/government/publications/escherichia-coli-e-coli-o157-annual-totals/shiga-toxin-producing-escherichia-coli-stec-data-2021).

Investigation of STEC infection in Laura Farmer (timeline)

16. UKHSA understands that on 24 April 2024 Mrs Farmer was admitted to University College London Hospitals (UCLH), having been transferred from Royal Surrey County Hospital with HUS following a history of four days of diarrhoeal illness ten days prior to admission.

17. On the same day, UKHSA London was informed that Mrs Farmer had tested positive for STEC (using polymerase chain reaction testing). UKHSA London immediately transferred Mrs Farmer's details to UKHSA South East for follow-up as a resident of the South East region.

18. On 25 April 2024 UKHSA South East spoke with nursing staff on the Intensive Treatment Unit (ITU) at UCLH and determined that Mrs Farmer was present on the ward and was well enough to be interviewed by UKHSA South East about her condition. UKHSA South East conducted the interview with Mrs Farmer by phone. This included undertaking an ESQ and gathering additional information to assess risk and to guide any recommended actions.

19. Mrs Farmer reported that all household contacts were well at the time of interview. No close contacts were in risk groups for gastrointestinal (GI) infection. It was noted that no person in the household was aged five or under and no person in the household was reported as unable to perform personal hygiene. Risk of transmission in the household was considered low and no testing or further public health actions were recommended for the household as per national guidance.

20. Infection prevention and control advice was provided verbally to Mrs Farmer at the time of the interview. UKHSA South East emailed Mrs Farmer after the interview confirming the advice and providing a factsheet, as per usual practice.

21. Mrs Farmer was asked all questions on the ESQ, which included details of contact with water and animals as well as eating out and contact with people with a gastrointestinal infection. Mrs Farmer identified one restaurant, a trip to a city within in the UK for work (although no food was eaten on this trip), a blocked drain in the house, and contact with domestic pets. She also outlined foods she had consumed prior to becoming unwell.

22. There were five specific details that Mrs Farmer was unsure of, and she requested that UKHSA South East send a follow up email outlining these questions so that she could ask her husband for more detail. This email was sent on the same day along with infection control advice.

23. On 26 April 2024 UKHSA South East called Mrs Farmer to ask whether she had obtained the additional information from her husband but was unable to make contact. On 29 April 2024 after further unsuccessful contacts UKHSA South East called UCLH ITU and was advised that Mrs Farmer had sadly and unexpectedly died.

24. The UKHSA staff member who made the follow-up call sought advice from senior colleagues at this time and it was agreed that no further contact should be made. UKHSA South East considered that the next of kin was grieving and that unnecessary contact could be considered intrusive at that time. UKHSA South East made the judgement not to speak to the next of kin on the basis that all public health actions had been completed, risk of ongoing transmission in the household was extremely low, both household contacts were well at the time of the interview, and that a significant time had elapsed since the onset of illness in Mrs Farmer.

25. On 29 April 2024 UKHSA South East uploaded the completed ESQ to its clinical information system and shared the completed ESQ with the local authority environmental health team for follow-up and risk assessment of specific settings. The environmental health team were advised that Mrs Farmer had died and were requested not to contact Mrs Farmer's next of kin. The environmental health team agreed to undertake a routine inspection of a restaurant attended by Mrs Farmer and conducted a risk assessment of other possible sources identified in the completed ESQ.

26. UKHSA South East also sent the completed ESQ to UKHSA's national GIFSOH team to review against exposure information for other cases. No other cases were identified with common exposures.

27. On 2 May 2024 the WGS result became available and the STEC subtype causing Mrs Farmer's illness was identified as STEC O26:H11. At the time three other cases were microbiologically linked (using WGS) to this case. UKHSA's GIFSOH team did a detailed review of the information available for these four cases and did not find any common links between these cases at the time nor any likely source of infection.

Contact with Mrs Farmer's next of kin

28. On 14 June 2024 UKHSA South East was contacted by Waverly Borough Council's environmental health team reporting that Mrs Farmer's next of kin had attended their offices on 13 June 2024 requesting further information on the investigation of Mrs Farmer's illness. The next of kin informed the environmental health officer that they had subsequently been unwell with diarrhoea after Mrs Farmer's death. As a precaution the environmental health officer arranged testing of the next of kin and their household.

29. On 14 June 2024 a UKHSA South East senior clinician called the next of kin to discuss their concerns further. The discussion included the role of UKHSA in case investigation, the timeline of actions taken by UKHSA following notification of Mrs Farmer's illness and the next of kin's concerns regarding lack of contact with them. The next of kin was advised that Mrs Farmer's illness was unrelated to any current or previous outbreaks of STEC. It was agreed that UKHSA would discuss the next of kin's concerns regarding contact with them in their next team clinical review to ensure any lessons were identified. It was also agreed that UKHSA would send the questionnaire to the next of kin for further completion.

30. On 14 June 2024 UKHSA South East sent the next of kin a copy of the ESQ previously completed with Mrs Farmer, asking for any helpful or relevant information to be added and emailed back to UKHSA South East. Information on UKHSA's complaints procedure was also shared by email.

31. On 20 June 2024 the results of the testing of the next of kin and their household were communicated to the next of kin and household by text – all results were negative.

32. There was no further contact between UKHSA South East and the next of kin.

Response to specific concerns raised by the Senior Coroner

Chief Coroner's Guidance

33. In accordance with the Chief Coroner's Guidance, Guidance No. 5 Reports to Prevent Future Deaths, there is a pre-condition that "*the coroner has considered all the documents, evidence and information that in the opinion of the coroner is relevant to the investigation"* (Regulation 28(3)). UKHSA acknowledges from the PFD report that the Senior Coroner did not call anyone from UKHSA to give evidence as she *"expected UKHSA to have shared relevant information with both clinicians and family."* We would respectfully draw attention to the fact that if UKHSA officials had been contacted, invited or UKHSA itself requested to be an Interested Person, we would have been able to provide the Senior Coroner with a more in-depth understanding of UKHSA's involvement, thus, making available additional evidence and documentation on which to base her recommendations. Without having the full extent of UKHSA's investigations at her disposal, our view is that not all the relevant evidence was considered. This may have gone some way into shaping the Senior Coroner's overall recommendations.

34. We acknowledge the Senior Coroner's expectation that UKHSA share relevant information with both clinicians and the family. However, without information about our role or any UKHSA representation at the inquest, we believe this expectation has led to an unfair observation. Paragraph 25 of The Chief Coroner's Guidance Note No.5 states that a Coroner, when reporting, should *"…base their report on clear evidence at the inquest or on clear information during the investigation, to express clearly and simply what that information or evidence is, and to ensure that a bereaved family's expectations are not raised unrealistically."* The lack of UKHSA evidence and representation at the inquest, in our view, would cause difficulty in expressing clearly and simply when, how and who information should have been disseminated to. This in turn would lead to bereaved family members relying on incorrect information and unfortunately believing dissemination processes were in place that were not in accordance with UKHSA's policies and procedures.

Review of practice

35. UKHSA is a learning organisation and commits to undertaking regular reviews of practice and ensuring learning is identified to support quality improvement.

36. UKHSA South East undertook an informal peer review of actions taken. The review concluded that all public health action had been completed for this case in line with the national guidance and standard practice and that the team had acted compassionately in their interactions with Mrs Farmer and subsequently with the next of kin.

37. It was concluded that it was appropriate for the team to speak directly with Mrs Farmer in this instance. The clinical team providing care to the patient confirmed that Mrs Farmer was well enough to speak to the UKHSA staff member at the time of the call and Mrs Farmer consented to the interview. She was assessed by the experienced UKHSA nurse administering the ESQ to be alert and well enough to complete the process. It is always preferable to undertake a risk assessment directly with the case if possible.

38. UKHSA South East asked all the questions contained in the ESQ, which includes a detailed food history as well as contact with animals and water. The investigation undertaken by the team was in line with national guidance and consistent with best practice. It should be noted that in many instances it is not possible to identify the source of infection for individuals and investigations can be lengthy and complex.

39. Infection prevention control advice was provided directly to Mrs Farmer at the time of interview. It was judged at the time that there was very low risk of infection to the household contacts therefore no further action was taken in line with national guidance and usual practice.

40. When UKHSA became aware that the next of kin had ongoing concerns about the management of this case, a senior member of the regional team made direct contact to provide additional information and answer questions raised.

41. The review identified one learning point in relation to dealing with unwell cases, namely that where a case is known to die during investigation a risk assessment should be undertaken in collaboration with the clinical team treating the case to determine whether additional contact should be made with the next of kin. Any consideration of the need for a grieving family for privacy should be weighed against the potential need for information. The contact details of the UKHSA regional team will be shared with immediate family so they can contact the regional team if they have any questions or would like to provide any further information.