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Investigation into an outbreak of *Listeria monocytogenes* infections associated with hospital-provided pre- prepared sandwiches, UK May to July 2019

October 2020

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Executive summary

On 7 May 2019, local investigations were intensified in North West England after two patients contracted listeriosis in the same hospital and subsequently died. Both patients had severe underlying medical conditions and were in hospital during their incubation periods. The patients had overlapping admission dates and common food exposures during this time. Hospital acquired infection was suspected and investigations into the food chain and food hygiene at the hospital were instigated. *L. monocytogenes* cultures from both cases were referred to Public Health England (PHE) for whole genome sequencing (WGS), and on 16 May 2019 the isolates were found to be genetically indistinguishable, and previously unobserved in the national surveillance system. On 15 and 20 May 2019, infection control investigations at the first hospital involved sampling of food handling areas, products prepared on-site and sold in outlets. Samples were referred to PHE FW&E microbiology services and *L. monocytogenes* was not detected. On 23 May 2019, *L. monocytogenes* from an inpatient with listeriosis at a different hospital in North West England was identified using WGS as the same strain, pointing to a common source of exposure.

On 24 May 2019, following the identification of the three cases of listeriosis in the North West linked by WGS, a review of food histories and the supply chain at both hospital trusts led to the primary hypothesis that the source of the infections was chicken mayonnaise sandwiches from a common supplier (Supplier X). Traceback indicated that Supplier X supplied sandwiches to 42 NHS Trusts. Early intervention included the voluntary withdrawal of products containing chicken from hospitals by Supplier X on the 25 May 2019 and the IMT advising affected Trusts on 26 May 2019 against serving all sandwiches distributed by Supplier X to vulnerable patients (contamination of other products could not be precluded).

Active case finding was instigated, involving the follow-up and referral of isolates from all probable cases of listeriosis for WGS. Between 16 May and 14 June 2019, nine confirmed cases of listeriosis associated with the outbreak were identified in England. All had underlying comorbidities and risk factors for listeriosis, and seven died. Onset dates ranged from 20 April to 2 June 2019. The median age of cases was 75 years, and six were female. Food histories for cases were investigated through interviewing cases (or proxies) and inspection of catering records where available. All nine cases had received care at hospitals supplied by Supplier X prior to onset, and the consumption of Supplier X prepacked sandwiches was confirmed for eight cases. Of these, six consumed chicken sandwiches and two reported consuming other sandwiches from Supplier X (including cheese and egg).

Following the descriptive evidence implicating chicken sandwiches, traceback investigations identified that meat was provided to Supplier X by a cooked meat producer, Producer Y. Both Supplier X and Producer Y had independently conducted regular routine sampling and testing of food and production environments through the same external laboratory service. Isolates of *L. monocytogenes* from unopened packs of cooked duck, chicken and ham, sampled from Supplier X's food environment, were detected by the external laboratory through routine testing on 25 April 2019. The isolates were referred to PHE GBRU for WGS on 7 June 2019, and an isolate from the chicken was confirmed as the outbreak strain on 10 June 2019.

PHE FW&E and local authority officers visited Supplier X to undertake sampling of the premises. On 28 May 2019, an unopened pack of diced chicken delivered to Supplier X from Producer Y's manufacturing environment was sampled. Unsatisfactory levels of *L. monocytogenes* according to EU regulations were detected (>100 cfu/g), and on 6 June 2019 the isolates were confirmed by WGS as the outbreak strain. On the same day, the outbreak strain was also identified from a coronation chicken sandwich sampled from a hospital on 30 May 2019. The sandwich had been supplied by Supplier X using cooked chicken from Producer Y. Sampling of various types of ingredients and the food processing environments of both the production and supplier sites during May and June 2020 recovered strains of *L. monocytogenes* of serotype 1/2a CC121 and 1/2c CC9, which were unrelated to the outbreak strain. The outbreak strain was not detected in the production environment at either Supplier X or Producer Y sites, however the detection of other strains unrelated to the outbreak indicated inadequate cleaning and hygiene. On 1 July 2019, PHE GBRU received *L. monocytogenes* isolates from the external laboratory service after a customer of Producer Y had submitted a food sample for testing. These isolates were referred to PHE for WGS and on 5 July 2019, the outbreak strain was confirmed in an isolate from diced bacon which had been manufactured at Producer Y.

Control measures undertaken in response to the outbreak at Supplier X included changing to an alternative chicken supplier on 28 May 2019, and voluntarily ceasing production on 5 June 2019, with a subsequent withdrawal of all products on 10 June 2019. On 3 June 2019, Producer Y implemented a positive release system for all products manufactured on-site. However, on 7 June 2019 the factory voluntarily ceased production, followed by a voluntary withdrawal of all cooked meat products distributed from its premises. On the 13 June 2019, food standards authorities in England, Wales and Scotland shared a guidance letter with local authorities providing advice on a sampling strategy for customers with detained products distributed by Producer Y.

Pre-prepared sandwiches served in hospitals have previously been implicated in outbreaks and cases of sporadic listeriosis, and are the most common food vehicle associated with listeriosis in England and Wales. Following the outbreak, the Secretary of State for Health and Social Care commissioned a "root and branch"

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review of food served in hospitals, while Salford City Council are continuing investigations into Producer Y in relation to their food safety management systems.

Abbreviations

BC	Borough Council
CC	Clonal complex
CCA	Central Competent Authority
cfu/g	Colony-forming units per gram
CNS	Central Nervous System
EH	Environmental Health
EHO	Environmental Health Officer
EPIS	Epidemic Intelligence Information System
FLCoP	Food Law Code of Practice
FS	Field Service
FSA	Food Standards Agency
FSS	Food Standards Scotland
FSW	Food Standards Agency Wales
FW&E	Food, Water and Environmental laboratories
GBRU	Gastrointestinal Bacteria Reference Unit
GI	Gastrointestinal
HACCP	Hazard Analysis and Critical Control Points
HPS	Health Protection Scotland
HPT	Health Protection Team
IMT	Incident management team
LA	Local authority
MFT	Manchester University NHS Foundation Trust
MLST	Multilocus sequence typing
MRA	Microbiological Risk Assessment
NHS	National Health Service
NIERP	National Incident and Emergency Response Plan
NIS	National Infection Service
PHE	Public Health England
PHW	Public Health Wales
RAN	Remedial action notice
RMA	Risk management advice
RTE	Ready-to-Eat
SERD	Science Evidence and Research Division
SNP	Single Nucleotide Polymorphism
ST	Sequence type
TARGET	Tuberculosis, Acute Respiratory, Gastrointestinal, Emerging /Zoonotic Infections, and Travel Division
WGS	Whole genome sequencing

1. Background

Listeriosis is an infection caused by the Gram-positive bacterium *Listeria monocytogenes* [1]. Listeriosis may present as mild self-limiting gastroenteritis with fever. However, in vulnerable individuals such as the elderly, neonates, immunocompromised, or pregnant women, infection can lead to invasive disease such as septicaemia, central nervous system (CNS) disease, foetal loss, or death [1, 2].

Listeriosis is a rare infection in England and Wales, with only 156 cases reported to national surveillance in 2018[3]. However, its clinical severity renders it a public health concern. Of all non-pregnancy associated cases reported to surveillance in England over a ten-year period, 70% presented to hospital with septicaemia, 22% presented with CNS involvement, and 12% presented with both CNS involvement and septicaemia [2]. Of all pregnant women with invasive listeriosis reported to surveillance in England and Wales during a 20-year period, over 20% suffered foetal deathAwofisayo, Amar [4].

L. monocytogenes is usually transmitted to humans via consumption of contaminated food[5]. The bacterium tolerates disinfectants and salt, low oxygen environments, and freezing, and grows at ideal refrigeration temperatures[1, 6]. In food production environments, it can establish biofilms on surfaces which can protect the bacteria from cleaning and disinfection[6]. Consequently, *L. monocytogenes* has been documented to persist on manufacturing equipment for years or even decades, increasing opportunities for cross-contamination[1, 7, 8]. There is a risk of *L. monocytogenes* in chilled ready-to-eat (RTE) foods, with outbreaks linked to cooked and sliced meats, cooked seafood, pre-packed cooked chicken, and pre-packed sandwiches[1, 3, 6, 8, 9]. Pre-prepared sandwiches served in hospital are the most commonly associated food vehicle for listeriosis in England and Wales [8].

The EU regulation on microbiological criteria sets a maximum limit for RTE foods able to support the growth of *L. monocytogenes* and those with a shelf life of less than five days of “not detected” in a 25g sample before the food has left the immediate control of the producer or, no more than 100 cfu/g of food at the end of the shelf life where this can be demonstrated by the manufacturer [10]. For healthcare settings, guidance from the Food Standards Agency (FSA) recommends limiting *L. monocytogenes* growth by managing cold chains and monitoring the shelf life [6].

Listeriosis has been a notifiable disease in England since 2010[2]. Public Health England (PHE) collects clinical and epidemiological data on all notified cases of listeriosis, and clinical isolates from listeriosis cases are referred to the Gastrointestinal Bacteria Reference Unit (GBRU) at PHE for confirmation and genetic typing. Since December 2015, all referred *L. monocytogenes* isolates undergo whole genome sequencing (WGS), which allows identification of genetically-linked isolates.

All cases of listeriosis in the UK are subject to a public health investigation and follow-up including a questionnaire on food exposures[3]. On 26 April 2019, Greater Manchester Health Protection Team at PHE were notified of the death of a case of listeriosis who had been admitted as an inpatient within Manchester University NHS Foundation Trust (MFT) in North West England. A second suspected case within the same hospital was notified on 4 May 2019. On 7 May 2019, local incident investigations were carried out within MFT following the death of the second inpatient.

Both patients were hospitalised during their incubation periods due to underlying medical conditions, with concurrent admissions and common food exposures during admission. Clinical isolates from both cases were referred to PHE for WGS, and on 16 May 2019 were found to be genetically indistinguishable *L. monocytogenes* that were previously undetected in England and Wales, indicating a common source of infection. Hospital-acquired infection was suspected and investigations into the food chain and food hygiene investigations at the hospital were instigated. On 23 May 2019, *L. monocytogenes* from an inpatient with listeriosis at another hospital in North West England was identified by WGS as the same strain, indicating a likely common foodborne exposure and that the vehicle of infection was distributed across different NHS Trusts. This report describes the subsequent outbreak investigations.

2. Incident co-ordination

On 21 May 2019, an Incident Management Team (IMT) was convened by PHE North West Health Protection Team, involving colleagues from the PHE National Infection Service (NIS), MFT, Manchester City Council (MCC) and the FSA.

An IMT meeting was held on 24 May 2019, including the NHS Trust and LA for the third case identified in North West England.

PHE NIS became national incident lead on 27 May 2019. The outbreak was declared as a standard incident under the PHE National Incident and Emergency Response Plan (NIERP).

A national IMT was convened that included representatives from relevant divisions of:

- PHE
- FSA
- Health Protection Scotland (HPS)
- NHS England
- NHS Scotland
- Public Health Wales (PHW)
- Food Standards Scotland (FSS)
- Food Standards Agency Wales (FSW)

- Stafford Borough Council
- Salford City Council
- local authority environmental health teams in the North West

Three operational cells (environmental investigation, communications, and epidemiology) were agreed and implemented on 30 May 2019. On 31 May 2019, the outbreak was escalated to an enhanced incident. On 5 June 2019, a microbiology cell was convened.

The Incident Director role was shared by the following roles during the enhanced incident:

- Deputy Director of the Tuberculosis, Acute Respiratory, Gastrointestinal, Emerging/Zoonotic Infections & Travel Health Division (TARGET)
- Consultant Medical Microbiologist (TARGET)
- Consultant, Acute Respiratory Infections (TARGET)
- Surveillance Lead, Gastrointestinal Infections (TARGET)

All incident related documents including meeting minutes and reports were stored in a dedicated folder on a secure PHE network drive.

A dedicated email account (opsroom.colindale@phe.gov.uk) was used to monitor all incident related communications. In addition, a dedicated email account for the epidemiology cell was created (epicellgi@phe.gov.uk) to monitor and manage communications related to the investigation. Access to the mailboxes and secured network drives were restricted to key members of the IMT.

The national IMT convened on 19 occasions between 29 May and 19 July 2019 and all meetings were held onsite at Colindale and by teleconference. Core members of the IMT are listed in the Appendix.

Food Law Enforcement

The FSA has a key role as the Central Competent Authority (CCA) in overseeing official food safety controls undertaken by LA food law enforcement authorities in England, Wales and Northern Ireland. It is important to understand that, in most cases, enforcement of food law is a direct statutory duty of the competent authority (in this case, the local authorities).

Responsibilities of LAs are set out in the 'Framework Agreement on the Delivery of Official Feed and Food Controls by Local Authorities' and the Food Law Code of Practice (FLCoP). The FLCoP is issued under section 40 of the Food Safety Act 1990,

Regulation 26 of the Food Safety and Hygiene (England) Regulations 2013, and Regulation 6 of the Official Feed and Food Controls (England) Regulations 2009, which empower the Secretary of State to issue codes of practice concerning the execution and enforcement of that legislation by Competent Authorities. It relates to England only. There are similar codes under the devolved equivalent regulations in Wales, Scotland and Northern Ireland. The FLCoP (published March 2017) outlines the definition of a food incident, and the roles and responsibilities of both the FSA and LAs for food incidents. Paragraph 2.2.2 of the code defines “a food incident” as “any event where, based on the information available, there are concerns about actual or suspected threats to the safety, quality or integrity of food that could require intervention to protect consumers' interests.”

The code outlines the obligations for competent authorities, (LAs in this case), to notify the FSA of outbreaks and other incidents. Specifically, the FSA Incidents Teams should be notified, without delay, of any incident where the hazard is either serious and localised or widespread. The FSA Incidents Team assigns an ‘incident classification’ by recognising and understanding the potential impact of an incident and then considering how the incident should be managed in terms of levels of resource, authority and priority. FSA classifies incidents into routine or non-routine. There is an FSA internal plan for management of routine incidents and a **published plan for the management of non-routine incidents**.

Levels of prioritisation exist within each incident classification which dictate prioritisation and framework for command and control response, in turn the level and seniority of resource and in which the incident is managed within the FSA. Using the FSA’s incident classification matrix outlined in the incident management plan (IMP), this incident was initially classified as a routine incident during the initial response. As new information became available, the classification was kept under review and the incident classification was escalated to a non-routine serious incident, which had a national impact, on 31 May 2019. On containment of the incident, it was de-escalated on 18 July 2019 from serious to routine.

3. Outbreak investigation methods

3.1. Epidemiological investigations

The objectives of the epidemiological investigation were to identify and describe cases associated with the outbreak, to identify and confirm the likely vehicle of infection.

Key strands of the epidemiological investigation included agreeing the outbreak case definition, case ascertainment, collection and review of epidemiological data for hypothesis generation and confirmation. Demographic and food history data were collected via a standardised questionnaire (**trawling questionnaire**) administered to the case or a proxy via Health Protection Teams, hospital staff or the LA. Additional information was requested from hospital staff on food histories whilst cases were inpatients from hospital patient records.

3.1.1. Case definitions

Microbiological typing results reported from the PHE GBRU were used for case finding and classification using the following definitions:

Confirmed: A clinical case of listeriosis[3], with laboratory-confirmed infection with the outbreak strain: *Listeria monocytogenes* serotype 1/2a, clonal complex 8 (CC8) with a SNP address of 4.6.34.265.297.308.%.

Probable: A clinical case of listeriosis with an onset date on or after 1 April 2019, awaiting further typing who attended a healthcare facility supplied by Supplier X during their incubation period*.

*Incubation period: inpatient or hospital visit within the exposure window according to Goulet[11]

- exposure window (non-pregnancy associated case) – 70 days prior to onset
- exposure window (pregnancy associated case) – 42 days prior to onset

3.2. Microbiological investigations

The objective of the microbiological investigations were to collect and characterise isolates of *L. monocytogenes* from cases, food and food production environments.

3.2.1. Clinical specimens

Isolates of presumptive *L. monocytogenes* from normally sterile sites (blood and/or CSF) were sent from hospital laboratories to GBRU. DNA was extracted from pure cultures received and submitted for WGS. For each isolate, the species identification, serogroup and multilocus sequence type (MLST), were derived from WGS data and isolates assigned to a clonal complex in accordance with the [Institut Pasteur international MLST database for *L. monocytogenes*](#). Reference mapping was performed against the CC8 specific reference strain CP006862. Hierarchical single linkage clustering was performed on the pairwise Single Nucleotide Polymorphism (SNP) difference between all strains at specific distance thresholds (250, 100, 50, 25, 10, 5, 0). The result of the clustering is a SNP profile, or SNP address, that can be used to describe the clonal groups of less than 5 SNP differences. The phylogeny was created based on a core SNP alignment using the CC8 reference genome CP006862 and accounting for recombination.

3.2.2. Food and environmental sampling

Food and environmental samples were obtained from food production environments by Environmental Health Practitioners and transported in accordance with FLCoP.

Microbiological testing of food and environmental samples was performed by the PHE FW&E microbiology laboratories in York and Colindale. The laboratories are official control laboratories ([as designated by the FSA](#)) and are UKAS accredited to ISO17025. The York laboratory covers the North of England and East Midlands, and the Colindale laboratory covers the South East and West Midlands.

Food samples of 25g were tested for both presence/absence and enumeration of *L. monocytogenes* (as well as other *Listeria* species) using the ISO11290-1:2017 and ISO11290-2:2017 methods. Food samples were taken from MFT, the implicated cooked meat producer (Producer Y), and the implicated sandwich producer (Supplier X). Environmental swabs from these premises were obtained by local authority staff from Manchester City Council, Stafford Borough Council and Salford City Council Environmental Health teams (EH) respectively.

Isolates of *L. monocytogenes* were sent to PHE GBRU at Colindale for WGS. Isolates of *L. monocytogenes* were also sent to GBRU for WGS from a commercial testing laboratory (isolates from products from Supplier X and Producer Y) and PHW FW&E laboratory (sandwiches collected from hospitals in Wales).

3.3. Food chain investigations

The objective of the food chain investigation was to identify the potential source of contamination and to determine the extent to which contaminated items were distributed.

3.3.1. Supply chain

Supply chain investigations were conducted by the FSA in conjunction with LAs for both Supplier X and Producer Y.

3.3.2. Meat preparation facility (Producer Y)

The factory where the sandwich meats were manufactured, Producer Y, was assessed by Salford EH to identify any contraventions in food safety legislation and to determine whether food produced there was unsafe. This involved:

- A physical inspection of the premises to assess the structure and cleanliness as well as observing handling and food safety practices;
- Assessing the suitability of the food safety management system via the Hazard Analysis and Critical Control Points (HACCP).
- Assessing the effectiveness of the implementation of the control and monitoring procedures. This usually involves reviewing production records, focussing on those that are critical to food safety to ensure that they are within safe limits
- Assessing the food safety knowledge of those responsible for the implementation of the HACCP and management of the system
- Identifying any failings in the production process that would have given rise to the contamination of meat products with *Listeria* spp.

The FSA required Producer Y to submit all production records for the six months prior to the incident (January to June 2019) for review, to identify any possible failures in points critical to food safety. Due to the sheer volume of information submitted to Salford EH, it was not possible to review every production record for every batch. As a result, Salford EH randomly selected records from batches over the six-month period to review in detail, in agreement with Manchester City Council Legal Team.

3.3.3. Sandwich preparation facility (Supplier X)

An initial food hygiene inspection of Supplier X was undertaken by Stafford BC in accordance with the requirements of the FLCoP (England) and internal Stafford BC inspection procedures accredited to ISO 9001 as described in the previous section (3.3.2).

Inspections were undertaken using a variety of techniques including:

- Questioning of owners/managers/staff in food hygiene procedures;

- Observation of the premises/equipment/staff;
- Temperature measurements taken of equipment;
- Audit of paperwork, HACCP and sampling results.

3.3.4. Hospital catering facilities

The FSA Incident lead officer liaised with the LAs for the hospitals affected by the outbreak to undertake investigations at the eight hospitals implicated in the outbreak. The investigations covered various aspects of food hygiene and safety reflecting specific requirements in Regulation (EC) No. 2073/2005 on the Microbiological criteria for foodstuffs, food hygiene in Regulation (EC) No. 852/2004 and general food law requirements in Regulation (EC) No. 178/2002. Specifically, the FSA asked the LAs for each of the eight hospitals to ascertain information regarding the general hygiene, shelf life, temperature controls and whether they were observing the principles outlined in FSA's guidance for *Reducing the Risk of Vulnerable Groups Contracting Listeriosis* [6] at the hospitals during the time of this outbreak. MFT conducted investigations of catering facilities, which included an audit of refrigerator storage and temperatures. EH officials from Manchester City Council (MCC) inspected catering facilities and processes at the hospital and collected food and environmental swabs on 14 May and 20 May 2019.

4. Results

4.1. Epidemiological investigations

Retrospective and prospective case ascertainment identified nine confirmed cases. The cases had onset dates between 20 April 2019 to 2 June 2019. The earliest onset date was 20 April 2019, and this case was not confirmed as part of the outbreak until 14 June 2019, due to the time for referral of the clinical isolate to GBRU.

Seven confirmed cases died during the course of the outbreak investigation. Six of the nine confirmed cases, including four of the deceased, were inpatients at the time of symptom onset. All nine confirmed cases had underlying health conditions. The median age of confirmed cases was 75 years (25% and 75% percentiles were 53 and 80 years). Six were female and three were male.

All nine confirmed cases had visited a healthcare facility during their incubation period, and had consumed sandwiches at either a hospital or healthcare facility. Cases were distributed across England in seven NHS Trusts.

Six out of nine confirmed cases reported consuming the implicated chicken sandwiches from Supplier X prior to illness onset, and two confirmed cases reported eating a different type of sandwich (egg and mayonnaise; cheese) from Supplier X within their incubation period (Table 1).

Table 1. Hospital-provided sandwiches eaten by confirmed cases within incubation period

Exposure	Confirmed cases
Supplier X chicken sandwich	6
Supplier X other sandwich	2
Other sandwich (Supplier X link uncertain)	1
Total	9

4.2. Microbiological investigations

WGS confirmed that isolates from all nine clinical cases' blood were within the same 5-SNP profile (CC8 t5.308). Maximum likelihood phylogeny showed the clustering of the nine outbreak cases and three food isolates against a background of 60 representative CC8 isolates in the PHE database encompassing the strain diversity collected through surveillance (England, Wales and Scotland isolates) from 2013 – 2019 (Appendix).

Seven out of the nine *L. monocytogenes* genomes isolated from clinical cases had zero SNPs differences between them. Isolates sampled from chicken at Supplier X, from a coronation chicken sandwich, and from diced bacon had indistinguishable SNP profiles, providing microbiological evidence of the common source of foodborne transmission.

Strains of *L. monocytogenes* isolated from two cases differed from the other cases by a single, isolate-specific SNP. Of these isolates, one strain had an indistinguishable SNP profile from an isolate recovered from diced chicken from Producer Y. The closest unrelated isolate to the outbreak strain in the PHE database was 17 SNPs away and was a clinical isolate from 2018.

4.3. Food chain investigations

4.3.1. Supply chain trace-back investigations

Upon notification that hospital-provided chicken and mayonnaise sandwiches were a common food exposure shared by the first three cases linked by WGS, Manchester City Council identified Supplier X as the supplier of the sandwiches.

The FSA informed the LA, Stafford Borough Council, as the home authority for Supplier X. The sandwiches had been supplied to 42 NHS Trusts distributed throughout England, Wales and Scotland. The supplier of the chicken used in the sandwiches was identified to be a meat producer, Producer Y and the respective LA home authority for this business, Salford City Council, was contacted to inform them and request environmental health investigations.

The FSA continued investigations further up the supply chain, focusing on the suppliers of products into the Meat Producer. Producer Y was the earliest point in the supply chain of cooked meats where *L. monocytogenes* matching the outbreak strain was detected from an unopened pack of chicken (Supplier X) and bacon (another customer of Producer Y).

4.3.2. Meat preparation facility (Producer Y)

Salford EH visited the Producer Y facilities on 11 occasions. The following production processes involved in the production of cooked meats were used:

- The cooking of raw joints of pork, beef, turkey and chicken
- Re-processing of cooked meat products, including duck
- Machine slicing and dicing of meat products cooked on site
- Machine slicing and dicing of pre-cooked meat products brought onto the site
- Hand slicing of meat products
- Shredding and pulling of meat products
- The wholesale supply of food products, although this was conducted via a distributor

None of the physical inspections carried out by Salford EH found any serious defects or failures in processing or handling. However, complex automated food contact machinery were used in Producer Y's premises and EH were concerned that such complex equipment cannot be fully stripped back for cleaning and disinfection.

In total, Salford EH reviewed production records for 19 batches, to identify any potential failures in HACCP and/or traceability. Every batch reviewed by Salford EH had some level of missing records and a number of discrepancies. Salford City Council are

continuing investigations into Producer Y in relation to their food safety management systems.

4.3.3. Sandwich preparation facility (Supplier X)

At Supplier X, no matters of concern were found during the initial inspection (May 2019). A number of further visits were made to the site in order to take food and environmental samples, supervise environmental cleaning and audit the sandwich manufacturing process in detail.

4.3.4. Hospital catering facilities

The inspection of catering facilities included the in-hospital facilities managed by an external catering company as well as three on-site retailers.

The FSA asked the appropriate LAs for each of the eight hospitals implicated in this outbreak to ascertain information regarding the general hygiene, shelf life and temperature controls for food in their hospitals during the time of this outbreak. The LAs reported that seven of the hospitals had a **food hygiene rating** of five upon the last inspections prior to the outbreak. The final hospital had received a food hygiene rating of two, as at 16 October 2018. However, a follow up inspection was carried out on 6 November 2018 and significant improvements had been made to structural and hygiene issues identified by the LA. The hospital was visited for inspection on 21 June 2019 in light of the outbreak, however there was no evidence of an update to the food hygiene rating.

The LAs were asked specific questions regarding the catering provision and HACCP plans in place and their effectiveness for each of the hospitals. Of the eight hospitals implicated in the outbreak, only three of them had specific controls for *Listeria* detailed in their HACCP plans, while the others stated that controls were general for chilled food storage and/or food poisoning bacteria. LAs were asked to analyse hospital temperature records for a two-month period (between April - June 2019, dependant on the exposure dates), to ascertain whether there had been any chilled equipment breakdowns during this time. The temperature and shelf life controls in place at each hospital identified that the FSA 2018 guidance for *Reducing the Risk of Vulnerable Groups Contracting Listeriosis* [6] was not being observed nor was there an alternative procedure in place to mitigate *Listeria*. Recommendations for improvements in sampling routines, hygiene and HACCP practices were made at each hospital. The audit of the refrigerators indicated the temperature CCP in place was ineffective to manage *Listeria*, at 8°C.

The LA for one of the hospitals detailed issues with the chilled display units, meaning there were instances when the temperature increased above 8°C. This was an apparent known issue in that hospital and the LA specified that during these occurrences use of the equipment would have been prohibited, including for high-risk foods.

The LAs were also asked how well the chill chain for RTE foods was managed within their hospitals. One of the most significant observations by one LA was that there were situations where cold chain temperature breaches were permitted (occurred with no evidence of intervention or corrective action), e.g. delivery, cold storage, picking and packing room food handling or preparation, transportation to wards, storage on wards and service. It was apparent that it was common practice across most of the hospitals to work towards a target temperature of 5°C with a critical limit of 8°C - too high to enable prevention of *Listeria* growth. At an LA investigation in the North West, the EHO reported that no effective temperature monitoring and recording procedure was in place but staff reported that they would have reported temperature breaches had they occurred. Fridge temperatures above 5°C and 8°C were identified at one hospital trust in the East Midlands, however these fridges had not been used to store sandwiches for the patient affected. However, the LA for another hospital trust in the East Midlands reported that the hospital had a critical limit of 5°C for sandwich deliveries, and deliveries above this temperature would be rejected. All of the LAs for the hospitals reported that the supplier of sandwiches for patient feeding had been Supplier X at the time of the notification of the outbreak. The LAs provided product specifications for sandwiches in their hospitals, with particular focus on the cold chain, shelf life requested and microbiological specification for *L. monocytogenes*.

Different hospitals had different procedures and specifications for shelf life. A maximum chilled shelf life of day of production plus 2 days should be applied, unless evidence of shelf life studies is provided to prove otherwise [6]. As *L. monocytogenes* can grow at refrigeration temperatures, if it was present in the product, an increased shelf life may pose an increased risk to the consumer. Two hospital trusts reported product specifications for sandwiches should have a shelf life of day of production plus 2 days. Other hospitals relied on NHS procurements to determine shelf life, which was day of production plus 3 days. The hospital HACCP plans had not considered this shelf life specification as a CCP. No evidence of shelf life studies was provided. On investigation, the shelf life was reduced to day of production plus 2 days.

Food businesses require registration with the local authority where they are located in. It was identified through the course of the incident investigations that two hospital trusts had not registered with the LA as a food business.

4.3.5. Food samples

Manchester University NHS Foundation Trust

On 15 and 20 May 2019, food was sampled from the hospital catering services, including food outlets and businesses situated on-site. Seventeen food samples were submitted to the York FW&E laboratory which included cooked meats, sandwiches, grated cheese, salad and pre-cut fruits. No *L. monocytogenes* or other *Listeria* species were detected in any food samples taken from MFT (Table 2).

Supplier X

Between 31 May and 5 June 2019, 28 food samples from Supplier X were submitted to the FW&E laboratory at Colindale which included cooked meats and sandwiches.

L. monocytogenes was detected in nine samples taken from Supplier X, of which five were sampled from an unopened pack of British diced chicken supplied by Producer Y (tested within shelf life). Unsatisfactory levels of *L. monocytogenes*, according to EU regulation, were detected in the diced chicken samples (1,100 – 3,500 cfu/g). The outbreak strain, serotype 1/2a CC8, was isolated from all five diced chicken samples from the same unopened package and was indistinguishable from the clinical isolates by WGS. A different strain of *L. monocytogenes*, serotype 1/2a CC121, was isolated from a chicken mayonnaise sandwich prepared on-site (Table 2).

Three isolates of *L. monocytogenes* from unopened packs of cooked duck, chicken and ham supplied to Supplier X from Producer Y, from routine testing undertaken by Supplier X's contracted laboratory on 25 April 2019 were referred to GBRU on 5 June 2019. On 10 June 2019, WGS confirmed the isolate from chicken as the outbreak strain.

Producer Y

Between 28 May and 29 July 2019, 28 food samples from Producer Y were submitted to the York FW&E laboratory and included packaged cooked meats or foods returned as part of a product withdrawal (Table 2).

L. monocytogenes was detected in 11 samples taken from Producer Y but were different strains to the outbreak strain (CC9 and CC121).

On 13 June and 1 July 2019, *L. monocytogenes* isolated from five foods were received by GBRU from an external testing laboratory who had tested products from Producer Y for another downstream customer. All five isolates were sampled from cooked meats produced by Producer Y. The outbreak strain was confirmed in one isolate sampled from diced bacon that was produced in April 2019. In the remaining four food isolates, a different strain of *L. monocytogenes*, serotype 1/2c CC9, was identified.

Table 2. Food sampling results, May – July 2019

Site	No. of food items sampled	<i>L. monocytogenes</i> detected
Producer Y	28*	16**
Supplier X	31†	9††
MFT	17	0

* 21/28 sampled after the voluntary closure of Producer Y site.
 ** 4/16 sampled before voluntary closure of Producer Y site and potentially could have entered the food chain; *L. monocytogenes* detected at <20 cfu/g.
 † 28/31 samples tested by PHE FW&E; 3/31 samples tested by external lab services and isolates submitted to PHE GBRU for WGS.
 †† *L. monocytogenes* detected in 5/9 samples at >10³ cfu/g (all samples from the same pack), and in one sample at <20 cfu/g (sandwich). *L. monocytogenes* detected in three isolates submitted to PHE GBRU for WGS from samples tested by external lab services.

4.3.6. Environmental samples

Manchester University NHS Foundation Trust

Thirteen environmental swab samples were taken from MFT from a variety of food and hand contact points. *L. monocytogenes* and other *Listeria* species were not detected in any of the environmental samples from MFT.

Supplier X and Producer Y

Between 28 May and 29 July 2019, 92 environmental swabs were taken from Producer Y, from machinery with direct contact with foods (e.g. dicers, slicers, conveyor belts) with a particular focus on difficult-to-clean areas. Hand contact points, cleaning equipment, drains, and other areas throughout the factory deemed to be potential harbourage sites for *Listeria* were also sampled. Between 28 May and 21 June 2019, a total of 61 environmental samples were taken from Supplier X, from similar areas as those described for Producer Y (Table 3).

L. monocytogenes was found in six environmental swabs taken from Producer Y and 11 environmental swabs taken from Supplier X (Table 3). There was evidence of environmental colonisation with at least two different strains of *L. monocytogenes* 1/2c CC9 within 10 SNPs of each other at Producer Y's premises. Similarly, environmental swabs taken from Supplier X also showed environmental colonisation with at least three different strains of *L. monocytogenes* serotype 1/2a CC121 which were within 25 SNPs of each other. These strains all differed from the outbreak strain, which was not detected in the environment of either premise.

Table 3. Environmental sampling results, May – July 2019

Site	No. of environmental samples	<i>L. monocytogenes</i> detected
Producer Y	92	6
Supplier X	61	11
MFT	13	0

5. Control measures

Product withdrawal

The FSA Incident lead officers sought risk management advice (RMA) from the appropriate policy team responsible for microbiological incidents along with expert input and risk assessment from Microbiological Risk Assessment (MRA) colleagues in FSA's Science Evidence and Research Division (SERD). On 25 May 2019, a teleconference meeting was held between the FSA Incidents leads and Policy colleagues along with Supplier X. This teleconference discussed the current situation, ongoing food supply chain investigations, as well as immediate actions to be undertaken by the Supplier X. This led to Supplier X undertaking a precautionary withdrawal of all patient products containing chicken; six product lines in total.

Article 19 of European General Food Law, Regulation (EC) No. 178/2002 defines when a product withdrawal is necessary and when a product recall is compulsory. A product withdrawal is when a product is removed from sale (i.e. taken off shelves) whilst a product recall is when product has been sold at retail and consumers are advised to take action such as return the product to where it was purchased. RMA leads advised Supplier X that a product withdrawal was required, and this was undertaken on 25 May 2019. No sandwiches had been sold at retail, therefore a product recall to alert consumers was unnecessary. The sandwiches had been supplied to 42 NHS Trusts, which were predominantly hospitals. Affected NHS Trusts were advised in a letter from the IMT on 26 May 2019 not to serve any products from Supplier X to vulnerable patients at risk of listeriosis, until further investigation and risk assessment were completed.

A product withdrawal of all ready-to-eat (RTE) meat products manufactured by Producer Y was undertaken on 7 June 2019. Subsequently, FSA and Food Standards Scotland (FSS) contacted LAs across England, Wales and Scotland for all customers of Producer Y's distributor, Distributer Z, and oversaw a full product withdrawal of potentially contaminated meat products produced by Producer Y. Salford EH witnessed the removal of returned products from Producer Y via an approved waste carrier for disposal.

Subsequently, FSA and FSS decided that verification of the effectiveness of Producer Y's product withdrawal was appropriate. Contact was made via priority communication to all LAs across England, Wales and Scotland. As a precautionary measure, those LAs with food businesses who had received products from Producer Y between January and May 2019 were asked to verify the product withdrawal was underway and to anticipate further direct contact with additional instructions .

On 7 June 2019, a priority notification letter was issued by FSA's Head of Incidents in England, subsequently followed by a letter from the Head of Consumer Protection in Wales in order to make the LAs aware of the outbreak, and to ascertain whether the food businesses within their jurisdiction had any product from Producer Y subject to the withdrawal on site. On 8 June 2019, all customers of Producer Y were contacted via their respective LAs; this included 61 food businesses in England, eight in Wales and three in Scotland.

Ongoing investigations identified that further food businesses had been implicated by the product withdrawal. On 13 and 26 June 2019, further priority notification letters were sent to the LAs of the food businesses to:

- request that they notify the FSA if recent routine inspections had identified products from the food businesses under investigation
- to alert the FSA if businesses in their area were customers of Producer Y
- ensure that unopened packs of RTE meats subject to the withdrawal be quarantined so that *L. monocytogenes* testing could be undertaken by PHE, PHW and HPS respectively. This was to determine whether the outbreak strain was present in other products
- to advise if the food businesses supplied to vulnerable groups (such as hospitals, care homes, nurseries). Additional businesses supplying or serving vulnerable groups were identified and this information was shared with PHE, HPS, PHW, and the NHS where additional NHS sites were identified.

Investigations were also undertaken into the suppliers of Producer Y to ascertain information on their business operations, as well as the products they supplied to Producer Y. This included whether they had identified any detections of *Listeria spp.* from food or the environment or in foods in the previous six months from their food safety management system controls and sampling undertaken to meet food safety legal obligations. There were no detections of *L. monocytogenes* reported.

5.1. Closure of implicated premises

On 5 June 2019, the owner of the sandwich manufacturing company, Supplier X, agreed to a voluntary closure. Supplier X remained closed until 21 June 2019, when Stafford BC officers reopened the site after extensive environmental swabbing which showed no detection of *Listeria* in the manufacturing environment. The company subsequently ceased trading on 28 June 2019.

Following the notification that the outbreak strain had been isolated in a batch of diced chicken produced by Producer Y in Salford and supplied to Supplier X in Stafford, Salford EH served a remedial action notice (RAN) preventing products from being

distributed, unless they were found to be satisfactory, following microbiological examination (positive release system). *L. monocytogenes* was detected in products Salford EH had sampled, which were on hold as part of the positive release system. Producer Y agreed to voluntarily close and Salford EH issued a voluntary prohibition notice, formalising the closure. Production ceased with immediate effect and did not recommence.

5.2. Communications

The outbreak required effective coordination among various stakeholder organisations. Briefings and materials were produced to provide timely and relevant information to NHS Trusts in England, PHE HPTs, and LAs, as well as UK Ministers and European public health agencies through Epidemic Intelligence Information System (EPIS).

On 7 June 2019, PHE and the FSA issued a joint press release announcing that they were working with other authorities to investigate cases of *Listeria* which had been linked to pre-packaged sandwiches:

- [PHE press release](#)
- [FSA press release](#)

On 14 June 2019, a [new release](#) announced that Producer Y had issued a withdrawal of products which may have been affected. A [further update](#) was provided by the FSA on 26 June 2019 which confirmed that Supplier X could restart production with an enhanced set of food safety measures in place.

6. Discussion and conclusions

This *L. monocytogenes* (CC8, t5.308) outbreak with nine confirmed cases was caused by contaminated sandwiches served at NHS hospitals in England in 2019. Of the nine cases, seven have died. The sandwiches were traced back to Supplier X, preparing the sandwiches and Producer Y, providing the cooked, diced chicken used to prepare the sandwiches. The outbreak strain was detected at high levels (>100 cfu/g) in unopened diced chicken packages sampled from the implicated sandwich company, Supplier X, originating from Producer Y. As well as providing microbiological evidence of a link to human infection, isolates submitted by the commercial laboratory confirmed cross contamination of cooked meats between the sandwich supplier and the meat producer.

Furthermore, the outbreak strain was isolated by laboratory services working for another customer of Producer Y from an unopened diced bacon sample. The outbreak strain was detected from several chicken-containing sandwiches from Supplier X and hospitals. Sampling of various types of ingredients and the food processing environments of both production sites identified strains of *L. monocytogenes* unrelated to the outbreak strain, including CC121 and CC9. The outbreak strain was not detected in any environmental samples at either Supplier X or Producer Y production sites, however, detection of environmental strains of other *Listeria* species (non-*L. monocytogenes*) indicated failings in the cleaning and hygiene.

One of the later cases reported consuming a cheese sandwich, which was produced by Supplier X but included no ingredients from Producer Y. These findings suggest that there may have been cross contamination and hygiene failures in both the Supplier X and Producer Y practises, therefore, it may be concluded that sandwiches from Supplier X were the direct source of the *L. monocytogenes* strain which caused this outbreak.

This is the eighth outbreak of listeriosis reported in England and Wales associated with sandwiches purchased from or provided in hospitals since 1999 [8, 12, 13]. Hospital food has caused listeriosis outbreaks in other countries, including pre-sliced meat jelly and butter in Finland[14, 15], desserts in Australia[16], delicatessen meat in Canada[17] and in Denmark[18]. Prepacked sandwiches are a common form of catering in hospitals in England and are a convenient alternative to hot food. However, sandwiches are complex food items with multiple ingredients and serve as a potential vehicle for *L. monocytogenes*[6, 15, 17, 18], a pathogen that can multiply and persist, particularly under suboptimal transportation or storage conditions.

WGS was critical during this investigation to link nationally dispersed cases, changing the context of the investigation from a single hospital outbreak to a national outbreak. Routinely collected information supported epidemiological investigations to rapidly identify the potential vehicle of infection, resulting in its withdrawal from the market on

25 May 2019 before microbiological confirmation of the outbreak strain in the chicken by WGS on 6 June 2019. Implementing control measures based on epidemiological evidence before microbiological confirmation in foods and/or the production environments reduced the possible exposure period by 12 days, which emphasizes the importance of enhanced surveillance for severe infections like listeriosis. The case with the earliest onset in the outbreak (20 April 2019) was not confirmed until 14 June 2019; clinical isolates from the patient were received by PHE GBRU for typing from the referring hospital on 7 June 2019. It is conceivable that earlier receipt of the isolate would have raised the possibility of a wider problem sooner and may have led to earlier intervention and prevention of some of the further cases in the outbreak. Referral of clinical isolates is on a voluntary basis and this observation illustrates the importance of rapid referral of all *Listeria* isolates for typing. Making such referrals mandatory should be actively considered.

From 1999 to 2011, nine of the eleven outbreaks reported to national surveillance in the UK were associated with hospital-provided food, eight of which involved sandwiches. The investigations revealed low-level contamination at the sandwich processing site, as well as inadequate temperature control upon delivery to the hospital. Surveys of hospital-provided sandwiches across the UK estimated prevalence of *L. monocytogenes* between 2.5% and 3.1%, with higher prevalence associated with prepacked sandwiches than sandwiches prepared on site[13].

Listeriosis contracted by consuming RTE meals in hospital is an ongoing food safety concern in many countries[19]. Due to the bacterium's ability to survive and grow in a wide range of food matrices, RTE food with low levels of *L. monocytogenes* at the production site may be sustained or grow during transport and storage to levels that pose a risk for immunocompromised patients. The findings from this outbreak investigation support previous recommendations that healthcare establishments should stipulate a criterion, to be met by manufacturers supplying sandwiches, of undetectable *L. monocytogenes* in sandwiches and their ingredients at the point of production[19, 20].

7. Acknowledgements

This report was written on behalf of the Incident Management Team. Our deepest condolences go out to the patients involved and the families of those who have died in this outbreak.

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Appendix

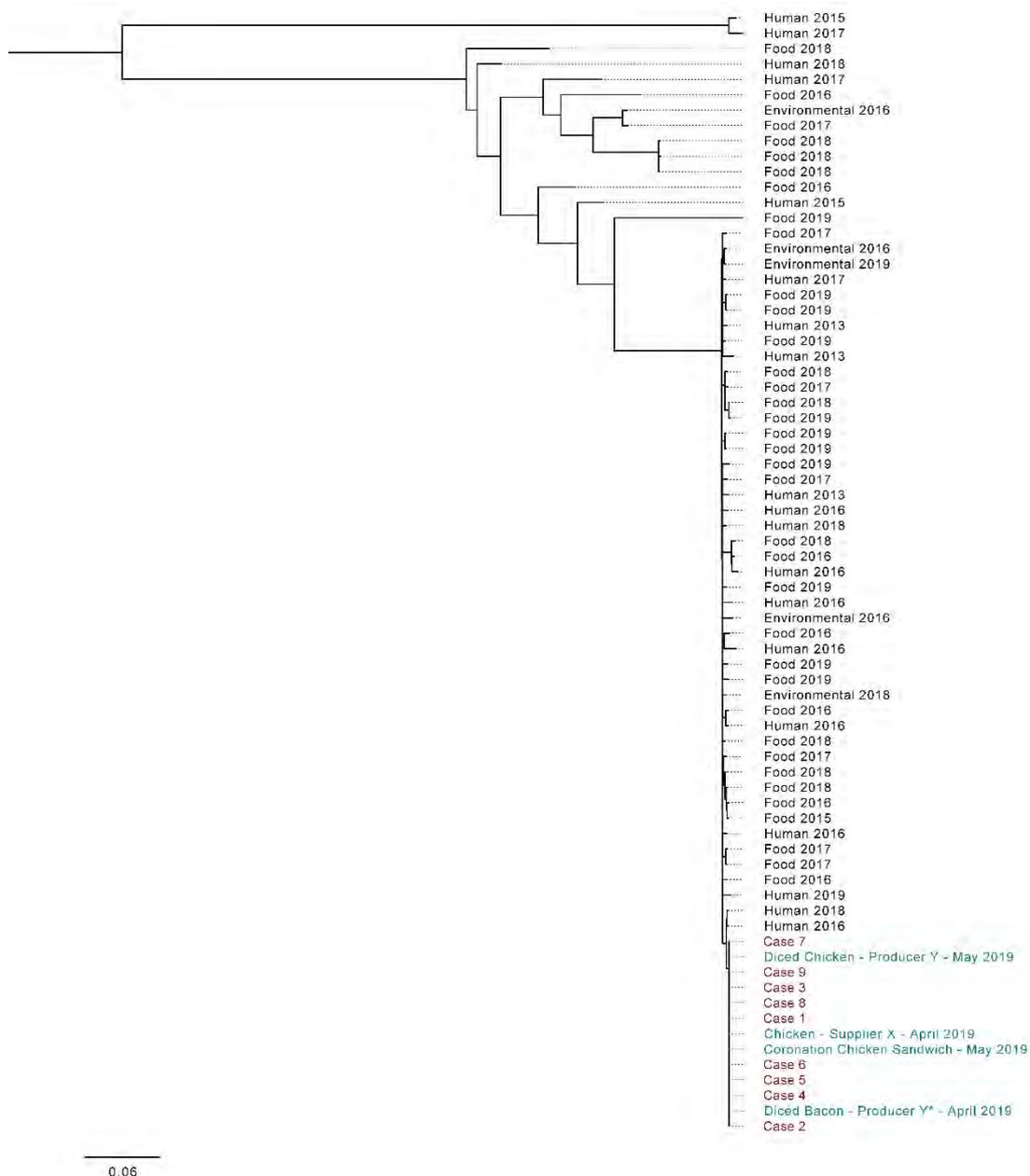
1. Core members of the IMT

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Lesley Larkin (Incident Director)	PHE – National Infection Service
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2. Maximum likelihood phylogenetic tree based on sequence variation (SNPs) with reference to *L. monocytogenes* CC8 (CP006862), 2019



Maximum likelihood phylogeny showed the clustering of the nine outbreak cases and three food isolates against a background of 60 representative CC8 isolates in the PHE database encompassing the strain diversity collected through surveillance

L. monocytogenes CC8 t5.308 outbreak cases are shown in red. Food isolates with indistinguishable SNP profiles from the outbreak cases are shown in teal.

*diced bacon isolate submitted by commercial laboratory, sampled from a customer of Producer Y

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