NHS Food Review

Food Safety Risk Profile

Contents

1 - Information request

1. To identify the relevant and relative food safety risks in hospital settings comparing the production of food on-site using fresh ingredients *vs* sourcing food prepacked from external suppliers.
2. To identify vulnerable consumers and relative food safety risks (where there is insufficient evidence, can refer to evidence from non-healthcare related settings). The risks reviewed should relate to foodborne disease in general, with a special emphasis on *Listeria monocytogenes*. Non-microbial food safety risks e.g. allergens, should also be considered
3. To identify evidence associating specific poor hygiene practices with incidents of foodborne disease, particularly in hospital settings (with a special emphasis on *Listeria monocytogenes*). To include reference to the Food Hygiene Ratings Scheme where appropriate.

2 - Summary

A risk profile, describing some of the possible food safety risks and adding context, has been produced. Based on outbreak data in hospitals, the microbiological scope of this profile has been established as *Listeria monocytogenes* contamination of sandwiches and salads. The risk profile of allergens is also considered. The theoretical risk pathways of food produced on-site in a hospital kitchen and production in a factory environment have been compared. Vulnerable populations have been identified, and their size and potential exposure has been estimated. Key evidence gaps and uncertainties have prevented further qualification of the relative risks of these two methods of production in the time available.

3 - Approach

This profile was produced between 2019-10-30 and 2019-11-15. Initial scoping determined that there was insufficient time and data to a complete a full risk assessment. A risk profile has therefore been produced. A risk profile, as defined by Codex Committee on Food Hygiene, is a description of a food safety problem and its context developed for the purpose of identifying those elements of a hazard or risk that are relevant to risk management decisions. A risk profile follows the basic outline of:

- Hazard identification – what is the hazard?
- Exposure assessment – how likely is the hazard to occur and to whom?
- Hazard characterisation – what are the consequences?

This risk profile is based on the data available during production. Further investigation could identify additional data that could fill some of the evidence gaps, allowing a more detailed risk assessment to be carried out. The scope could also be widened to cover other foodborne hazards.

4 - Hazard identification

To facilitate a rapid review of the evidence available regarding foodborne disease in healthcare settings, outbreak data from Public Health England (PHE), covering England and Wales, was considered. In order to refine the scope, only foodborne outbreaks categorised by PHE as 'hospital' were included and was date limited to 2004 onwards, to coincide with the introduction of Regulation (EC) 852/2004 on the hygiene of foodstuffs.

Between 2004 and 2019 there were sixteen foodborne outbreaks in hospitals, caused by six different confirmed causative agents and involving three confirmed food types, as shown in Table 1. Whilst all outbreaks are a cause for concern, those food products and causative agents that have proven to be recurring issues highlight more general food safety issues that should be tackled as a priority. Therefore, only food products and causative agents that have been implicated in combination in more than one foodborne outbreak since 2004 will be considered further.

Table 1: Outbreaks in hospital environments by food products, 2004-2019. Data provided by PHE

Causative agent	Composite/ mixed foods	Poultry meat	Eggs and egg products	Unknown
Campylobacter	0	0	0	1
Listeria	6	0	0	0
Norovirus	0	0	0	1
Salmonella	0	1	1	2
Scombrotoxin	1	0	0	0
Shigella	0	0	0	1
Unknown	0	0	0	2

Only one combination of food category and causative agent has been implicated in more than one foodborne outbreak since 2004: *Listeria monocytogenes (L. monocytogenes*) and composite/mixed foods. The composite foods implicated in these six outbreaks were sandwiches and salads, with all six outbreaks implicating sandwiches, and two implicating salads. Whether both sandwiches and salads were implicated in these two outbreaks, or whether the investigation only narrowed down to these two categories, is unknown in the time available. Therefore, the microbiological risk profile is based on the following food-pathogen combinations:

1. *L. monocytogenes* and sandwiches
2. *L. monocytogenes* and salads

5 - Exposure Assessment

5.1 - Risk pathway – occurrence of the hazard in the food chain.

Two microbiological risk pathways have been compared in Table 2, which consider two hypothetical methods of food production generated by ad-hoc expert elicitation.

The same pathways, although not focussed on a food product, have been considered for allergenic risk in Table 3. The 'off-site' pathway considers the production of salads and sandwiches in an established factory and assuming full compliance with industry standards. The 'on-site' pathway assumes that production of salads and sandwiches takes place in a hospital catering kitchen, which supplies only the hospital in which it is located, with less capacity and smaller scale production than in the factory setting.

The two pathways are theoretical in nature and serve to highlight the possible risks at each stage. They are not directly applicable at a national level, nor do they represent the average, as they are towards the hypothetical extremes. They are not exhaustive and within this risk profile it is not possible to produce a risk ranking or scoring exercise. Therefore, whilst one pathway may have more apparent risk factors highlighted, this does not equate to a higher relative risk. The potential risks identified could however be used as a framework for the construction of more localised, bespoke pathways following comparison of these hypothetical pathways with the reality of the local food chain.

The consumer populations in a hospital fall into three main groups: patients, staff and visitors. Not all food in a hospital is provided by the hospital catering department; there may also be retail outlets, vending machines and food brought in by visitors for themselves and patients. These foods are all outside of the scope of this profile, which will focus on food provided by hospital catering to patients on the ward. The proportion of each population consuming foods from the different sources is unknown and likely to vary between hospitals. This profile will therefore focus on the patient population, which is at highest risk as it reasonable to assume that this population will contain the largest proportion of vulnerable groups.

Table 2: Microbiological risk pathways for hypothetical "off-site" and "on-site" production of ready-to-eat (RTE) sandwiches and salads used in a hospital setting for distribution to in-patients on a ward

Stage	Pathway	Off-site – Pathway description, highlighting risk factors	On-site – Pathway description, highlighting risk factors
Upstream of production	Supplier	Regular supplier in large volumes, although ingredients may be variable throughout the year. May be a long chain of supply upstream	Supply may be more variable; may change supplier as needed, although supplier would have to be accredited
	Delivery	Assumed consistent delivery with a defined process.	If ingredient supply is variable, delivery could also be variable
	Traceability	Regular large volume supplier – likely good traceability	Irregular supply could limit traceability, especially from smaller

Stage	Pathway	Off-site – Pathway description, highlighting risk factors	On-site – Pathway description, highlighting risk factors
			companies or ad-hoc purchases
Production environment	Cross-contamination – HACCP plans	More detailed and thorough	Unlikely to be specialised
	Ingredient nature	If pre-cooked there would be a lower overall microbial load than in fresh ingredients, but for *L. monocytogenes* specifically, pre-cooked ingredients may be a higher risk as it is able to survive freezer temperatures and grow at refrigeration temperatures	
	Ingredient storage - usage	Regular turnover, standardised usage. High volume and diversity of ingredients, which may affect traceability	Irregular turnover, products may be more likely to be used up to the end of shelf life.
	Ingredient storage - temperature	Dedicated storage and industrial refrigeration	Industrial refrigerators? Maintenance of appropriate temperatures
	Human-food touches	Higher mechanisation – fewer human-food touches	Manual processing more likely – more human-food touches
	Washing	Decontamination – chemical or water-based. Potential for cross-contamination.	
	Cross-contamination	Multiple product lines – requires effective separation	Separation may be less possible due to space restrictions
	Storage – post-production	Defined, separated areas. Chill-chain maintenance	Separation may be less possible – higher risk of cross-contamination
	Shelf life	May have a longer shelf life due to preservatives and packaging. Regular testing of products	Likely shorter shelf life. Assumed less frequent testing of products and the environment.
	Staff training and hygiene practices	Specialised production – may have implemented specific controls	Greater variability in food products – may have less experience with certain high-risk foods
	Cleaning	May have dedicated staff. Intense and rigorous with swabbing regime. Harder to fully disinfect mechanised	Less likely to have dedicated staff. Swabbing regime unknown. Food

Stage	Pathway	Off-site – Pathway description, highlighting risk factors	On-site – Pathway description, highlighting risk factors
		system – biofilm formation	production environment may be easier to clean
	Surface area	Large surface area with potential for contamination –chance of biofilm formation and recontamination	Smaller surface area – chance for biofilm formation and recontamination
Transfer to end distributor	Chill chain	Dedicated storage, maintenance of chill chain	N/A – products are already within the hospital
	Storage	Longer storage time post-manufacture could allow *L. monocytogenes* growth	
	Delivery	Assumed standardised process. May be an issue with handover – temperature control	
Distribution within hospital	Temperature control	Maintenance of temperature in fridges in central storage and peripheral storage – commercial vs domestic fridges	
	Chill chain	Maintenance of chill chain – refrigerated transport?	
	Separation	Separation in central and peripheral storage – thought unlikely	
	Traceability	Labelling of products – at what stage might labels be removed?	
	Cross-contamination	Packaging reduces the risk of cross-contamination in storage/display at point of purchase. Packaging status in the hospital is uncertain	
Time with consumer	Traceability	Recording of consumption and matching to batches unlikely	
	Delivery	Distribution system - chill chain maintained throughout?	
	Temperature abuse	Time between delivery and consumption – enforced? Temperature control on wards unlikely	
	Discard	Guidelines on timing and enforcement?	

Table 3: Allergen risk pathways for off-site and on-site production of food in a hospital setting

Stage	Pathway	Off-site – Pathway description, highlighting risk factors	On-site – Pathway description, highlighting risk factors
Production environment	Cross-contamination – HACCP plans	More detailed and thorough	Unlikely to be specialised
	Cross-contamination	Spatial and temporal separation of production lines	Separation may be harder to achieve
Distribution within hospital	Cross-contamination	Packaging reduces the risk of cross-contamination in storage/display at point of purchase	Packaging status uncertain – potential risk for cross-contamination at display and point of purchase
Time with consumer	Labelling	Must be provided on the packaging, up front information to allow informed choices	Labelling may not be supplied with food, although it must be available upon request
	Precautionary labelling (risk has been identified but cannot be effectively managed at production)	If present on the packaging, up front information to allow informed choices	Potential for dynamic/changing ingredients in production could lead to inaccurate information

5.2 - Pathogen/food characteristics

Listeria spp. other than *L. monocytogenes* are rarely pathogenic. *Listeria* spp. are ubiquitous in the environment and can grow and survive in soil, water, foods and the food production environment, and are frequently present in raw foods of both plant and animal origin. *L. monocytogenes* can grow at temperatures ranging from low refrigeration temperatures up to 45 °C and can grow in low oxygen environments, for example modified atmosphere packaging (MAP) used for RTE foods. Growth does not occur below pH 4.2 or in foods with a water activity of less than 0.92. Freezing does not kill *L. monocytogenes,* but the organism is unable to grow at freezer temperatures (-20 °C). Whilst cooking temperatures higher than 65°C kills the bacteria, a temperature of 70°C for 2 minutes achieves at least a 6-log reduction. There can be issues with cross-contamination of RTE products from raw products, or issues with eliminating the pathogen from product that cannot be heat treated, for example fresh produce.

L. monocytogenes is able to form biofilms which are hard to remove and can persist in the food production environment, where it can contaminate or re-contaminate food

products. Additionally, biofilms decrease the effectiveness of disinfectants/sanitisers on *Listeria* spp. (Fagerlund, 2017). *Listeria* spp. have also been found to resist the action of certain disinfectants, such as quaternary ammonium compounds, again decreasing the effectiveness of disinfectants/sanitisers (Martínez-Suárez, 2017).

Due to the ability of *L. monocytogenes* to grow at refrigeration temperatures, it is a notable risk in RTE chilled foods and particularly those with a long shelf life, such as sliced meats or certain cheeses, and items that cannot be cooked to remove all contamination, such as fresh produce. Growth accelerates once these products are held above refrigeration temperatures. Washing of lettuce and other salad items will remove some but not all bacteria present on these products.

5.3 - Scale of exposure

5.3.1 - Sandwich and salad production in the UK

The number of sandwiches produced yearly in the UK is approximately 4 billion (British Sandwich Association, 2018). If it is assumed that sandwich consumption is the same across the UK then, proportional to population, that would mean that 3.56 billion UK-produced sandwiches are consumed in England and Wales each year. Greencore, a large producer, purportedly produces on average nearly 2 million sandwiches a day at 16 different sites (Greencore website). The average production per day at each site would therefore be in the region of 100,000 sandwiches. The annual consumption of (uncooked) leafy green meals in England and Wales is 5.2 billion (years 1-8 of NDNS survey data; proportional to the population of England and Wales). However, these data are for the total population and may not be representative of hospital catering.

5.3.2 - Food production in the NHS

21 million Finished Consultant Episodes (a period of care for a patient under a single consultant at a single hospital) were recorded in the financial year 2017-2018 in the NHS in England and Wales (NHS Digital, NHS Wales). 10.2 million of these patients were aged 60 or over. The number of in-patient main meals requested in England in the financial year 2018-2019 was 140.9 million (ERIC Report on NHS Digital). Data for Wales could not be found in the timescale provided. Broad classification of hospital site practice into ‘on-site’ produced meals and delivered (‘off-site’ produced) meals is shown in Table 4. ‘On-site’ meal production includes ‘cook-serve’ catering where the meal is cooked from scratch on the premises and ‘on-site central production unit’, where meals are prepared and then chilled or frozen for use on-site or for delivery elsewhere. Use of these data would mean around 64.8 million meals produced on-site and then served, or chilled or frozen for later use, and 76.1 million delivered meals. Hospital episode statistics shows that the median length of stay in hospital, for all diagnoses, is four days, therefore it is likely that patients are exposed to sandwiches or salads on multiple occasions during a stay.

Table 4: Data for food service type for NHS hospitals in England that serve food to in-patients, broken down by meals cooked on-site and meals produced off-site (categorised in datasets as delivered meals, PLACE 2018).

	Number of sites	Percentage
Meals produced on-site	428	46%
Meals produced off-site	499	54%
Total	927	100%

The number of meals in hospitals that include sandwiches or salads is unknown, due to the variability in hospital menus. The number and variety of meals consumed by in-patients which were brought in by visitors or from commercial premises in hospitals are also unknown. The meals provided to and consumed by out-patients is unknown. The size of the hospital population that is vulnerable to food allergens is unknown.

5.3.3 - The Food Hygiene Rating Scheme and foodborne disease

An investigation into the correlations between foodborne outbreaks and the Food Hygiene Rating Scheme (FHRS) rating of food businesses showed that establishments in England, Wales and Northern Ireland with higher (better) FHRS rating are less likely to have unsatisfactory sample results. Similarly, foodborne outbreaks are less likely to occur at establishments with higher FHRS ratings. Although it is not possible to identify hospitals specifically, considering caring premises as a whole, 85.1% have an equivalent FHRS rating of 5 (very good) and 99.1% have an equivalent FHRS rating of 3 (generally satisfactory) or above. These compare to 71.1% and 95.6% for all establishment types respectively. This data is from September 2019.

5.3.4 - Vulnerable groups

According to the Advisory Committee on the Microbiological Safety of Food report on listeriosis incidence, vulnerability to listeriosis is increased in those aged over 60, cancer patients, immunosuppressed patients, unborn and newly-delivered infants, pregnant women and those with other underlying medical conditions. The total population and figures for the size of vulnerable groups, where possible, are given in Table 5.

Table 5: Population statistics for England and Wales.

	Total Number	Source
Total population	59,115,809	Office for National Statistics, 2018
Population 60 or over	14,065,272	Office for National Statistics, 2018
Population under 1 year	669,797	Office for National Statistics, 2018

	Total Number	Source
Number of conceptions	847,204	Office for National Statistics, 2017

Population statistics for vulnerable groups other than these could not be found in the time available. If approximately 25% of the England and Wales population is considered as “vulnerable” (the proportion of population that is over 60 or pregnant), the number of sandwich or salad meals consumed by this population in total (all settings including hospital) would be in the order of 2.2 billion per year. The size of these populations within hospitals is unknown.

5.3.5 - Exposure summary

The estimated vulnerable population, for groups where data is available, in England and Wales is around 15 million. The number of hospital admissions was estimated to be around 17.4 million over the financial year 2017-18, although this figure is uncertain and would likely include multiple in-patient episodes by some individuals.

In England and Wales, the number of salads meals consumed per year was 5.26 billion, and the number of sandwiches totalling 3.56 billion. The number of sandwich and salad meals consumed by vulnerable groups is estimated to be at least 2.2 billion per year. The number of inpatient main meals requested in England in 2018/19 was 140.9 million with 46% of these being produced on-site with the rest (54%) being delivered. The total number of salads and sandwiches, and the number provided as in-patient meals, consumed by in-patients in hospitals is unknown.

6 - Hazard characterisation

6.1 - Incidence

Foodborne listeriosis is a rare disease in comparison to other foodborne pathogens, with only 135 cases in England and Wales in 2017 (PHE, 2018a). This compares to 8630 cases of *Salmonella* in 2016 (PHE, 2018b).These numbers are broadly similar to data from previous years, with the average from 2006-2016 being 178 cases per year (PHE, 2018c). The incubation time can be up to 90 days, which hinders diagnosis and source attribution, although the incubation period in some vulnerable groups can be much shorter.

6.2 - Susceptible populations

Listeriosis mainly affects certain vulnerable groups such as: adults over 60, those with underlying medical conditions, immunocompromised individuals, neonates, pregnant women and their unborn children.

6.3 - Outcome of exposure and severity

Clinical manifestations associated with listeriosis can be grouped into two categories: invasive listeriosis and non-invasive listeriosis. Symptoms of non-invasive listeriosis include mild flu-like or gastroenteritis symptoms, such as nausea, vomiting, fever, headache, myalgia and diarrhoea. Non-invasive listeriosis outbreaks generally involve the ingestion of high doses of *L. monocytogenes* by otherwise healthy individuals. Invasive listeriosis can lead to more serious infections such as meningitis

and other life-threatening complications, with a fatality rate of 20-30%. In vulnerable populations, *L. monocytogenes* is a significant cause of septicaemia and meningitis.

Quality Adjusted Life Years (QALYs) are a generic measure of disease burden, which takes into account both the quantity and quality of life lived - measuring the quality of the remaining years of life for an individual. An FSA project calculated the QALYs lost due to listeriosis in the UK. This work showed that *L. monocytogenes* reports the highest QALY loss compared to other pathogens at 4.034. For comparison, in the same study the foodborne pathogen *Campylobacter* reports a QALY loss of 0.260. To put this in context an individual who would otherwise live to the age of 80 in good health would only enjoy 75.97 years of good health after discounting for the QALY loss.

6.4 - Dose-response

Dose-response data from human volunteer studies with *L. monocytogene*s or from volunteer studies with a surrogate pathogen do not exist. The average probability of a single *L. monocytogenes* CFU to cause illness in a specific host (the *r* value) reflects the strain virulence and host susceptibility. The *r* value can range 5 orders of magnitude from the least to the most susceptible subpopulations, as estimated from outbreak data and expert elicitation (EFSA, 2017). As a result, there is no single value for infectious dose.

There are however certain medications that are known to increase the risk of listeriosis. Immuno-compromised individuals are a population vulnerable to infection by most pathogens, therefore any treatments that suppress the immune system, such as those for autoimmune disorders or following transplants, as well as cancer chemotherapy, increase the risk. With regards to *L. monocytogenes* specifically, there is evidence that patients taking medication to combat excess stomach acid (proton pump inhibitors) are at a greater risk of infection from *L. monocytogenes*. In 2014 it was estimated that 15% of the UK adult population had been prescribed proton pump inhibitors (Othman *et al.*, 2016). It is unknown how many in-patients are prescribed proton pump inhibitors.

7 - Conclusion

Data on foodborne outbreaks in hospitals identified *L. monocytogenes* in sandwiches and salads as the most common cause of foodborne outbreaks in hospital settings. The allergen profile did not focus on any specific food products or allergens.

The scale of exposure could not be fully quantified due to a variety of evidence gaps. It is known how many in-patient meals were requested and that currently meals are produced both on and off site across the NHS. It is also known how many sandwiches and salads are consumed by the UK population. It is not however known how many sandwiches and salads are consumed by in-patients. Whilst a standardised menu for food does not appear to exist across the NHS, a breakdown of food categories would be needed to make a more meaningful assessment of the potential exposure of vulnerable groups to allergens and *L. monocytogenes*.

An investigation into the correlation between foodborne outbreaks and the Food Hygiene Rating Scheme showed that outbreaks were less likely to occur in

establishments with higher ratings, and that caring premises were more highly rated on average than other establishments.

The risk pathways that have been generated are hypothetical and serve to highlight the possible risks associated with different stages of food production and consumption. It is not possible to produce a risk ranking that indicates the relative risks of each pathway. Therefore, whilst one pathway may have more apparent risks highlighted, this does not equate to a higher relative risk. To obtain a risk ranking and therefore a relative risk, structured expert elicitation could be considered.

8 - Uncertainties and Evidence gaps

This is a high-level profile with many gaps, which have prevented further qualification of the relative risk between the two pathways identified. These can be split into two categories; uncertainties with data that is referenced and gaps where data was not available during the production of this profile. It is likely that a more in-depth investigation could provide some of the data listed below.

8.1 - Uncertainties

- Outbreak data – the data used relies on PHE categorisation of outbreaks into 'foodborne' and 'hospital' and has not been verified.
- The risk pathways are theoretical and are based on ad-hoc expert elicitation. It is thought likely that experts consulted have more knowledge of factory production environments than hospital kitchens, which may have biased their responses.
- The definition of 'on-site' versus 'off-site' catering is not set
- The number of Finished Consultant Episodes is used as a proxy for the number of patients in the NHS but does not take into account repeat visits and so is likely an over-estimation.
- The type of catering in hospitals is listed in official data as a variety of categories that have been collapsed into 'on-site' and 'off-site' for the purposes of this profile. It is therefore uncertain how applicable these categories are.
- The data from the Food Hygiene Rating Scheme can only be broken down to caring premises, not to hospitals specifically.

8.2 - Evidence gaps

The following data could not be obtained during production of this risk profile:

- Source attribution of all *L. monocytogenes* outbreaks in England and Wales from 2004 to present
- Number of sandwich meals served to in-patients in hospitals
- Number of salad meals served to in-patients in hospitals

- Profile of in-patient diet across hospital catering, retail outlets and visitor-supplied food
- Number of repeat stays in hospital
- Identification of most likely food allergens present in hospital food and environment
- Size of vulnerable populations to food allergens in hospital
- Size of vulnerable populations for *L. monocytogenes* infection– cancer patients, immunosuppressed patients and those with other underlying medical conditions
- There is no single value for the infectious dose of *L. monocytogenes*
- It is unknown how many in-patients are prescribed proton pump inhibitors
- It is unknown whether sandwiches and salads are provided to patients with safety and allergen labelling