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Impact of molecular point-of-care testing on surveillance and public health management of invasive meningococcal disease

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ABSTRACT

Objectives: To assess the use of fully integrated, molecular point-of-care testing (POCT) platforms for meningitis diagnosis in England, and its impact on invasive meningococcal disease (IMD) surveillance and strain characterization. Case confirmation and strain characterization, important for informing the public health response, is often not possible following POCT.

Methods: The use of POCT for meningitis diagnosis was determined using a survey of English microbiology laboratories. Furthermore, national laboratory and public health databases were used to identify IMD cases diagnosed by POCT-only, without characterization, from 2022 to 2024.

Results: The survey indicated that at least 23 laboratories were using a POCT platform for meningitis diagnosis in 2024. Between 2022 and 2024, 1009 cases of IMD were confirmed, and we identified 14 confirmed only by POCT, increasing from 1 in 2022 to 9 in 2024. All POCT-only cases were notified to the local health protection teams; however, crucial public health actions may have been missed.

Conclusion: Although the number of IMD cases confirmed solely by POCT remains low, use of POCT is increasing. The impact on IMD surveillance, strain characterization and public health response must be carefully monitored to ensure that case management, outbreak detection and national disease trends are not adversely affected.

Background

Invasive meningococcal disease (IMD), caused by *Neisseria meningitidis* (the meningococcus), is a serious bacterial infection with sudden onset, rapid progression and high morbidity and mortality [1]. The meningococcus typically resides asymptomatically in the nasopharynx of approximately 10% of the general population [2]. Rarely, however, invasive disease can occur, usually manifesting as meningitis and/or septicaemia. There are 12 meningococcal capsular groups, classified by their distinct capsular polysaccharide composition, with serogroups A, B, C, W, X and Y being responsible for the vast majority of IMD cases worldwide. Vaccination is the most effective preventive measure against IMD [3]. A national routine infant MenB immunization programme and an adolescent MenACWY vaccine programme were both implemented in 2015. Globally, COVID-19 lockdowns and pandemic restrictions in 2020 and 2021 led to reductions in transmission of bacterial infections, including in IMD cases [4]. As restrictions were lifted, cases have gradually increased over time.

Prompt public health action in response to IMD is essential for prevention of secondary cases. In most countries, including the UK, the United States and European Union, this typically involves chemoprophylaxis of close contacts to clear existing carriage, and can sometimes also involve vaccination to provide long-term immune protection [5–9]. Meningococcal strain characterization provides crucial information to inform which public health actions should be taken [10–12]. Determining the serogroup of the invasive strain, for example, is critical for vaccine selection [13,14]. Without this, targeted vaccination of close contacts cannot be implemented. Additionally, further strain typing data provides invaluable evidence when investigating outbreaks and clusters, particularly in the absence of clear epidemiological links between cases,

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and in protracted outbreaks [12,15,16]. As across most of Europe, serogroup B meningococci (MenB) are responsible for most IMD cases in England [17,18]. Licensed protein-based MenB vaccines are therefore increasingly deployed for outbreak management, but their complex antigenic protein compositions lead to varying levels of strain coverage [19]. To assess whether a given vaccine is likely to cover a particular MenB outbreak strain, detailed phenotypic and/or genotypic characterization is required, dependent on prompt submission of clinical material (isolates and specimens) to the relevant specialist reference laboratory [20,21]. Viable isolates enable phenotypic characterization – including capsular and surface antigen expression, antimicrobial susceptibility testing and genome sequence analysis, which facilitates high-resolution phylogenetic analyses [14]. Characterization of meningococci directly from clinical samples (e.g. blood and CSF) is more challenging and generally restricted to genotypic analysis; however, several non-culture sequencing techniques are available, including direct genome sequencing through targeted DNA enrichment [22,23].

Whilst strain characterization supports the public health response for IMD cases, timely laboratory confirmation of IMD remains crucial for effective clinical management. Culture remains the diagnostic gold standard, but usually requires 24-48 hours. Molecular diagnostics are used to provide much faster and more sensitive IMD detection; however, due to the cost and technical requirements, these PCR-based assays are typically provided only by centralized laboratories at regional or national level. This lack of local provision can add to delays and reduce the timeliness of laboratory confirmation. To address this, several molecular point-of-care testing (POCT) diagnostic platforms have been introduced, which integrate DNA extraction and PCR-based detection within a single closed platform in order to provide rapid detection of meningitis and encephalitis pathogens. The reduced technical requirements of these platforms facilitates their use within the smaller, local hospital laboratories or even on hospital wards; however, the cost can still be prohibitive at this level. In England, the more commonly used POCT meningitis platforms include BIOFIRE FILMARRAY Meningitis/Encephalitis (ME) Panel (Biomerieux) and QIAstat-Dx ME Panel (Qiagenne) [24,25]. Both provide rapid detection of a wide variety of bacterial, viral and fungal targets, directly from the cerebrospinal fluid (CSF), typically in as little as 2 hours [24]. Although notification and treatment for IMD should be commenced immediately upon clinical suspicion, rapid testing could reduce delays in the response for rare cases with atypical presentation. Currently, these platforms are only used for testing CSF samples, but IMD can manifest as septicaemia with or without other focus of infection (e.g. meningitis, septic arthritis, pneumonia). Patient samples other than CSF, such as blood, joint fluid or sputum samples, are not validated with these tests.

Whilst providing rapid IMD diagnosis, these tests deplete the entire CSF sample without provision for retrieval of residual samples or DNA extraction. As a result, there is often no material left for diagnosis confirmation or strain characterization. This has significant implications for public health management, identification of clusters and vaccine programme surveillance.

Here, we present national data on the increasing adoption of these molecular POCT platforms for meningitis diagnosis in England. We consider their impact on meningococcal characterization and IMD surveillance, as well as the public health management of cases with suspected IMD and their close contacts.

Methods

IMD surveillance

In England, the UKHSA conducts enhanced national surveillance of IMD as described previously [26]. Briefly, registered medical practitioners are required to notify their local UKHSA Health Protection Teams (HPTs) of any case of suspected IMD or bacterial meningitis as soon as possible, and all suspected cases are then automatically recorded in the Case and Incident Management System (CIMS) (previously HPZone) dataset. Following any local testing, National Health Service (NHS) laboratories then routinely submit invasive meningococcal isolates to the UKHSA MRU for confirmation and characterization, including whole genome sequencing, antibiotic resistance testing and serogrouping. The MRU also provides a free national PCR-testing service for meningococcal detection and genogrouping directly from clinical samples from patients with suspected IMD. All local and MRU meningococcal confirmation tests will be recorded in the Second Generation Surveillance System (SGSS) dataset, thus representing all tests performed at all clinical laboratories across England.

Public health management of suspected IMD cases and their close contacts

The UKHSA publishes and regularly updates national guidance on the public health management of patients with suspected IMD and their close contacts [27]. HPTs, along with the UKHSA surveillance team, are responsible for identifying and managing local outbreaks of IMD. Timely notification of all suspected cases to the local UKHSA HPT is required so that urgent risk assessment can be performed and antibiotic chemoprophylaxis can offered to close contacts to prevent secondary IMD cases. Notifications to the HPTs are routinely recorded in CIMS, a national electronic case management system. HPTs also work with hospital teams to ensure all relevant samples are submitted to the UKHSA MRU for confirmation and characterization. Additionally, following confirmed MenA, MenC, MenW or MenY cases, the patient and their close contacts are offered the MenACWY conjugate vaccine to provide longer-term protection against these serogroups. For MenB cases, because two doses given at least 4 weeks apart are needed for protection, 4CMenB vaccination is not offered to close contacts of a single case (although MenB vaccination of cases and contacts may be considered for clusters and outbreaks). Finally,

National survey of molecular diagnostic testing

A national electronic survey was conducted to determine the number of microbiology laboratories in England that use a molecular-based platform for meningitis diagnosis. Between August 2024 and January 2025, the regional heads of laboratory services were requested to email the survey to the 115 microbiology laboratories in England, asking for details of any molecular platforms currently used, or possibly to be introduced soon, for meningitis diagnostics.

Responses were assessed and platforms/tests were characterized by platform type into either ‘traditional extraction/PCR’, in which the DNA extraction is separate to the PCR detection and therefore allows retention of the DNA extract, or ‘point-of-care testing (POCT)’ which refers to fully automated, cartridge-based molecular diagnostic systems that integrate nucleic acid extraction, amplification and detection within a single closed platform. The only two such POCT platforms identified were the BIOFIRE FILMARRAY and QIAstat-Dx.

Case audit

Data from a national electronic laboratory reporting system (SGSS) were extracted to identify all meningococcal-positive molecular tests for IMD in England from 1 January 2022 to 31 December 2024 (36 months). This dataset was then matched to the national MRU-confirmed IMD surveillance dataset to assess

Table 1
Invasive meningococcal disease (IMD) cases confirmed by the UK Health Security Agency (UKHSA) national Meningococcal Reference Unit (MRU) in England, by year and serogroup, 1 January 2022 to 31 December 2024.

Serogroup/year	2022	2023	2024	Total
A	1	0	0	1
C	4	4	4	12
W	9	10	26	45
Y	7	17	12	36
ACWY subtotal	**21**	**31**	**42**	**94**
B	227	355	312	894
Others (E, Z)	1	0	1	2
Ungrouped/NG	8	9	2	19
Other subtotal	**236**	**364**	**315**	**915**
Total	**257**	**395**	**357**	**1009**

Table 2
The results of the national survey on the use of point-of-care testing platforms for meningitis in National Health Service (NHS) hospital laboratories.

English region (total number of labs in the region)	Platform type		
	Traditional extraction/PCR	Biofire	QiaStat
East Midlands ($n = 7$)	1[a]	1	3
East of England ($n = 13$)	1	1	
North West ($n = 16$)	1	5	1
North East ($n = 7$)		3	
London ($n = 21$)	2[b]		
South East ($n = 16$)	1	1	
South West ($n = 12$)	2[a]	1	1
West Midlands ($n = 11$)		5	
Yorkshire and the Humber ($n = 12$)		1	
Total: ($n = 115$)	**8**	**18**	**5**

Numbers indicate the number of responses and the type of point-of-care platforms for each English region.
[a] Viral targets only.
[b] Viral and 16S-based sequencing.

whether samples from laboratory-confirmed IMD cases had been submitted to the MRU for species confirmation and characterization. Cases reported in SGSS without a positive sample recorded in the MRU surveillance dataset were followed-up with the local hospital laboratory to identify the method of diagnosis confirmation and, where cases were confirmed by a molecular POCT test, to obtain details of the testing platform.

Results

IMD surveillance

During 2022-2024, there were 1009 IMD cases confirmed by the MRU. MenB was responsible for 88.6% (894 of 1009) of cases, while 9.3% (94 of 1009) were caused by serogroups A, C, W and Y (1 MenA, 12 MenC, 45 MenW and 36 MenY). Two were other serogroups (E and Z) and the remaining 1.9% (19 of 1009) of cases were ungrouped/ungroupable (Table 1).

Survey results

Survey responses were received from 23 of 115 individual laboratories contacted electronically. An additional eight laboratories were contacted directly as part of the case audit follow-up and confirmed the use of molecular meningitis diagnostic platforms. In total, we identified 31 services that were using molecular POCT or traditional PCR tests on CSF samples to diagnose meningitis (Table 2). The scope of each service varied widely from laboratories covering a single hospital site to those providing microbiology laboratory services to multiple NHS trusts. Twenty-three laboratories were using a POCT platform, including 18 running BIOFIRE FILMARRAY ME Panel, and 5 running QIAstat-Dx ME Panel.

In addition to the 23 laboratories already using a POCT platform, five other survey respondents indicated they were interested in introducing, or actively in the process of establishing, a new molecular platform (three BIOFIRE FILMARRAY ME Panels, one QIAstat-Dx ME Panel and one undecided on the platform).

Audit of cases confirmed by POCT-only

During the 3-year surveillance period, we identified 14 IMD cases confirmed using POCT platforms only (BIOFIRE FILMARRAY ME or QIAstat-Dx ME). These cases were missing strain characterization, having not been referred to the MRU or having been referred but unable to be confirmed as IMD by the MRU (Table 3). Notably, although the number of cases confirmed by POCT-only was low in comparison to total IMD cases, those confirmed only by this method increased from one case during 2022 to four in 2023 and nine in 2024 (Figure 1). These cases all had a clinical diagnosis of meningitis and/or septicaemia, and they all had lumbar puncture performed and cerebrospinal fluid taken for diagnosis of suspected bacterial meningitis. The patients resided in different regions across England, their age ranged from 5 years to $\geq$65 years, and they all survived their infection. All cases were notified to the local UKHSA HPTs, a risk assessment was performed, and antibiotic prophylaxis was offered to all close contacts identified. Six of the 14 patients had a blood sample submitted to the MRU for PCR testing, all of which were negative for N. meningitidis. None of the 14 patients had a CSF sample submitted to the MRU for diagnosis confirmation, suggesting the sample is likely to have been depleted during testing. Since there were no positive tests for these patients at the MRU, the serogroup responsible was not identified and close contacts did not receive any vaccination for longer-term protection against IMD beyond the protection offered by the antibiotic chemoprophylaxis.

Among MRU-confirmed IMD cases in the national surveillance dataset, we did identify three additional cases in 2024 where a sample that had been tested on a POCT platform was forwarded to the MRU for diagnosis confirmation and further characterization. All three had been tested on the BIOFIRE FILMARRAY ME platform, with two returning a positive result, one negative. One of these patients subsequently had a positive blood culture for *N. meningitidis*, and the isolate was submitted to the MRU for confirmation and characterization. The other two patients had blood samples submitted to the MRU for PCR testing, and both were positive for *N. meningitidis*. All three strains were subsequently identified as MenB by the MRU.

Discussion

The use of molecular POCT platforms can significantly reduce the time taken to identify the causative pathogen causing serious clinical infections such as bacterial meningitis, with the potential to improve clinical care, optimize antibiotic use, decrease hospitalization length and stays, and potentially lower healthcare costs for the NHS [24]. For meningitis specifically, rapid diagnosis and early identification of the causative pathogen allows tailoring of the choice and duration of antibiotics to improve clinical outcomes. Despite these benefits, the use of these platforms can have downstream implications for public health response. The integrated design of the hardware means that, unlike traditional PCR platforms with separate DNA extraction, residual material or DNA extract can't be recovered from the test cartridge. In this study, over a 3-year surveillance period in England, we identified 14 IMD cases confirmed solely on a CSF sample by molecular POCT platforms with no samples forwarded to the reference laboratory. Con-

Table 3
Point-of-care testing (POCT) confirmed invasive meningococcal disease (IMD) cases with no positive sample submitted to the Meningococcal Reference Unit (MRU) in England from 1 January 2022 to 31 December 2024.

Case	MRU samples	Age	Region	Sample date	Sample	Alive	Notified	Public health actions	Clinical details
1	None	25-44	South East	Dec-22	CSF	Y	HPZ	1CC, chemoprophylaxis completed	Meningitis
2	None	45-64	Yorks and Humber	Jan-23	CSF	Y	HPZ	3CCs (2 children), chemoprophylaxis completed	Meningitis
3	Negative blood PCR	20-24	North East	Oct-23	CSF	Y	HPZ	4CCs, chemoprophylaxis completed	Septicaemia
4	None	15-19	West Midlands	Nov-23	CSF	Y	HPZ	5CCs, chemoprophylaxis completed	Meningitis
5	Negative blood PCR	15-19	South and West	Nov-23	CSF	Y	HPZ	5CCs, chemoprophylaxis completed	Meningitis
6	Negative blood PCR	5-9	North East	Jan-24	CSF	Y	HPZ	3CCs (1 child), chemoprophylaxis completed	Meningitis
7	Negative blood PCR	5-9	Yorks and Humber	Jan-24	CSF	Y	HPZ	5CCs (3 children), chemoprophylaxis not completed	Meningitis and sepsis
8	Negative blood PCR	25-44	East Midlands	Jan-24	CSF	Y	HPZ	1CC, chemoprophylaxis completed	Meningitis
9	Negative blood PCR	5-9	West Midlands	Mar-24	CSF	Y	HPZ	2CCs, chemoprophylaxis completed	Meningitis
10	None	65+	West Midlands	Mar-24	CSF	Y	HPZ	1CC, chemoprophylaxis completed	Meningitis
11	None	20-24	North East	Apr-24	CSF	Y	HPZ	2CCs + 4 ambulance crew, chemoprophylaxis completed	Meningitis
12	None	25-44	West Midlands	Oct-24	CSF	Y	CIMS	1CC, chemoprophylaxis completed	Meningitis
13	None	45-64	West Midlands	Nov-24	CSF	Y	CIMS	3CCs, chemoprophylaxis instigated	Encephalitis
14	None	65+	North East	Nov-24	CSF	Y	CIMS	4CCs (2 children and 1 newborn), chemoprophylaxis completed	Meningitis and encephalitis

CC, close contact.

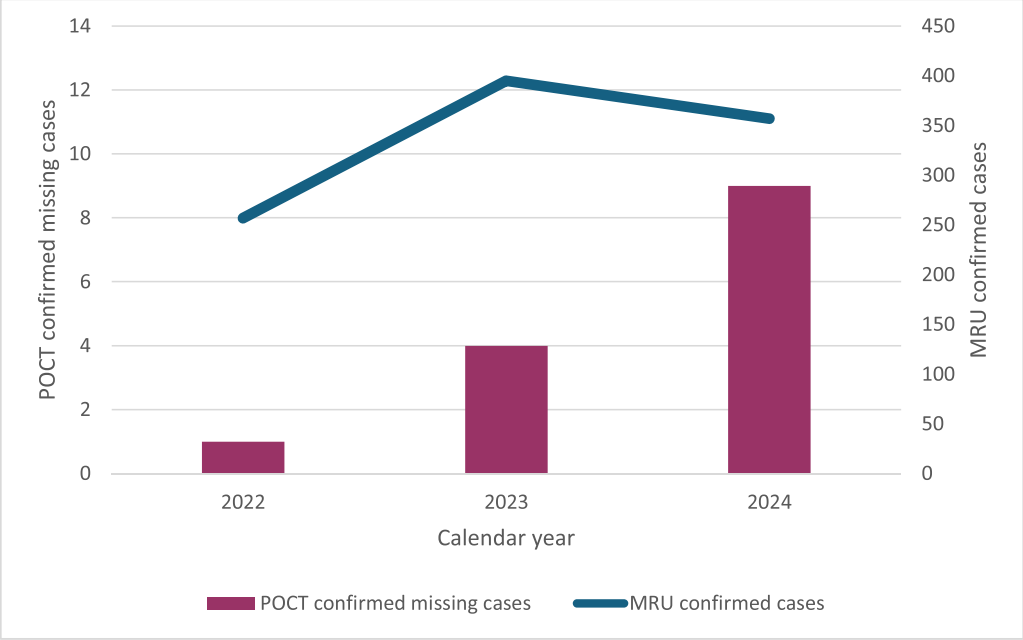

Figure 1. Invasive meningococcal disease (IMD) cases confirmed by the Meningococcal Reference Unit (MRU) vs IMD cases confirmed by point-of-care diagnostic testing platforms, missing strain characterization, by year, from 1 January 2022 to 31 December 2024.

sequently, for all 14 cases, it was not possible to confirm the diagnosis, identify the serogroup responsible or perform further strain characterization. Notification was made to the public health teams for all cases, and basic chemoprophylaxis was performed; however, vaccination was not arranged for any close contacts.

The specific reasons why samples were not forwarded in each case could not be determined but after confirming a case using POCT, laboratories will be reliant on unused sample being available because no residual DNA extract is accessible. Interestingly, the age distribution of these 14 cases was skewed towards older children and adults – none were under 5 years old. This is surprising given that younger children typically yield lower volumes of CSF during lumbar puncture and would therefore be more prone to sample depletion. This finding suggests that the amount of CSF sample collected may not be inherently restrictive. Instead, the amount provided to the laboratory team performing the POCT may only meet the minimum assay requirement (e.g. 200 µL). Additional unused sample may be available in other laboratories/departments (e.g. biochemistry), but retrieving this may be difficult or impractical. Without the ability to retrieve the DNA extract from the POCT cartridge, positive material will not be available for referral. Finally, in some cases, the issue could be procedural, with laboratories not having the relevant protocols in place for automatic sample referral for cases confirmed by POCT. Referral of culture isolates to reference laboratories is a well-established practice in most microbiology laboratories; however, the corresponding protocols for submission of PCR-positive specimens may not in place.

Whilst these cases represent only a small proportion of laboratory-confirmed IMD cases in England, the evidence suggests the use of molecular POCT platforms is expanding. These POCT-only cases were widely distributed across several English regions; this is consistent with survey results suggesting POCT plat-

forms have been established in laboratories throughout the country, many of which cover multiple hospital sites. Our survey was focussed on microbiology laboratories, although these platforms are designed to be used with minimal laboratory skills/training, so their use closer to the bedside (e.g. hospital wards) has been evaluated. Whilst the comparatively high cost is prohibitive, studies have suggested increased testing costs can be offset by reduced antimicrobial use and/or reduced length of stay [28,29]. Future work to determine the scale of POCT use in such settings, and an assessment of implications for downstream microbiological testing, would be invaluable.

Recommendations

In the light of these findings, and with anticipation of increase POCT use in the future, the following recommendations have been devised with the aim of facilitating sample referral for meningococcal strain characterization:

1. Maximal CSF sample volume should be collected (within safe clinical guidelines) to ensure enough material is available for all required testing, including additional material for strain characterization.
2. Laboratory protocols for automatic collection and referral of unused CSF (and other meningococcal-positive material) to the relevant reference laboratory should be established. CSF should be collected from other laboratories (e.g. biochemistry) if required.
3. Ensure that a bacterial throat swab is obtained for all patients with suspected IMD (meningitis and/or septicaemia). Although a positive throat swab alone is not sufficient for diagnosis of IMD, obtaining a meningococcal isolate in a patient with a positive PCR test or POCT would allow for additional strain characterization, including serogrouping and whole genome sequencing of the isolate [27,30].
4. Where possible, submit EDTA or, alternatively, any remaining blood sample to the reference laboratory for PCR testing (if available). Detection of meningococci from blood is often possible in meningitis cases and can provide crucial material for strain characterization.

Conclusions

POCT diagnostic platforms are increasingly being used by hospital laboratories in England to diagnose meningitis and rapidly identify the responsible pathogens in the CSF. Whilst this has obvious patient benefits, the lack of additional strain information poses new challenges for public health management of cases and close contacts and national surveillance. We have made several recommendations to help mitigate these problems, which we hope will be taken into consideration by hospitals that use or are planning to use POCT platforms for rapid diagnosis of meningitis. Further research on the recovery of lysate from POCT diagnostic platforms for additional strain characterization would be highly beneficial.

Author contributions

EH, HC and SR contributed national epidemiology and surveillance data, SC, RB, JL, and XB contributed laboratory analysis and typing. EH lead the case audit. SC lead the laboratory survey. SL contributed clinical insight and expertise. EH and SC drafted the paper. All authors reviewed and agreed the final version.

Ethical approval

UKHSA has legal permission to process confidential information for the purpose of national surveillance of communicable diseases without individual patient consent (Regulation 3 of Health Service Regulations 2002), and so ethics committee approval is not required.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Authors JL, SAC, RB and XB perform contract work on behalf of UKHSA for GSK, PATH, Pfizer and Sanofi. SNL performs contract work on behalf of St. George's University of London for vaccine manufacturers. The Immunization and Vaccine Preventable Diseases Division at UKHSA (authors EJH, HC, SR and SNL) has provided vaccine manufacturers with post-marketing surveillance reports on meningococcal, Haemophilus influenzae and pneumococcal infections, which the companies are required to submit to the UK Licensing Authority in compliance with their risk management strategy. A cost recovery charge is made for these reports. Author AF has no conflicts of interest.

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