



REVIEW

Range of Clinical Manifestations Caused by Invasive Meningococcal Disease Due to Serogroup W: A Systematic Review

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Received: June 6, 2023 / Accepted: September 1, 2023 / Published online: September 26, 2023
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ABSTRACT

Introduction: Invasive meningococcal disease (IMD) due to serogroup W meningococci (MenW) is consistently reported with atypical clinical manifestations, including gastrointestinal symptoms, bacteremic pneumonia, and septic arthritis. We undertook a systematic review of the literature for a comprehensive assessment of the clinical presentation of IMD caused by MenW.

Methods: PubMed and Embase databases were searched from inception to June 2022 using a combination of MeSH terms and free text for

articles that reported symptoms and signs of MenW IMD, and associated manifestations.

Results: The most commonly reported symptoms identified included: fever (range 36–100% of cases), nausea and/or vomiting (range 38–47%), vomiting (range 14–68%), cough (range 7–57%), sore throat (range 13–34%), headache (range 7–50%), diarrhea (range 8–47%), altered consciousness/mental status (range 7–38%), stiff neck (range 7–54%), and nausea (range 7–20%). Sepsis (range 15–83% of cases) was the most commonly reported manifestation followed by meningitis (range 5–72%), sepsis and meningitis (range 6–74%), bacteremic pneumonia (range 4–24%), arthritis (range 1–15%), and other manifestations (e.g., pharyngitis/epiglottitis/supraglottitis/tonsillitis/conjunctivitis; range 1–24%). The case fatality

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s40121-023-00869-z>.

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rates ranged from 8–40%, and among the survivors 4–14% had long-term sequelae.

Conclusions: Clinicians need to be aware of the nonspecific symptoms and signs of IMD, as well as of the atypical manifestations in regions where MenW is known to circulate to ensure timely diagnoses and treatment.

Keywords: Invasive meningococcal disease; Serogroup W; Symptoms

Key Summary Points

Meningococcal serogroup W (MenW) has increasingly become a cause of invasive meningococcal disease (IMD).

However, a high proportion of cases of IMD due to MenW may have atypical clinical manifestations.

We undertook a systematic literature review to comprehensively assess the reported clinical presentations of IMD due to MenW.

Although most cases of MenW disease have typical IMD symptoms, atypical presentations (pneumonia, arthritis, and upper respiratory/ophthalmological presentations) were reported in a sizeable proportion of cases.

To aid timely diagnosis and treatment, clinicians should be aware of the full spectrum of MenW IMD presentations.

INTRODUCTION

Neisseria meningitidis (*N. meningitidis*) is a commensal obligate human pathogen and a frequent colonizer of the nasopharyngeal mucosa, with 5–10% asymptomatic carriage rates at any given time [1, 2]. Adolescents are considered the principal reservoir and the most likely source of transmission [3, 4]. *N. meningitidis* can be responsible for invasive meningococcal disease (IMD), with an overall notification rate in Europe of 0.6 per 100,000 population between

2015 and 2017 [5]. The processes leading to IMD are not fully understood, but usually start on acquisition of invasive isolates [6], leading to serious morbidity associated with 10–15% fatality rates even with appropriate treatment [7]. Among those who survive IMD, 10–20% will have long-term disability [8].

To date, there have been 12 *N. meningitidis* serogroups identified, based on the immunologic reactivity of their polysaccharide capsule [9, 10]. However, almost all IMD cases are caused by serogroups A, B, C, W, X, and Y [1, 7]. The distribution and frequency of the six epidemiologically relevant serogroups varies by region, over time, and host age-group [11]. Most regions have experienced a decline in the incidence of IMD in recent years due mainly to the success of vaccination programs [11–13]. A further decrease also occurred upon the implementation of containment measures to control the coronavirus disease 2019 (COVID-19) pandemic [14].

Serogroup W has a relatively recent history in the epidemiology of *N. meningitidis*. After its first description in the late 1960s [15], reports of IMD caused by serogroup W (MenW) remained sporadic. Its role, on an international scale, was first described in 2000 with the epidemic among pilgrims to Mecca and their contacts [16]. This “Hajj” epidemic included cases of MenW of clonal complex 11 (cc11) [17]. As pilgrims returned to their countries of origin, the “Hajj” strains (later named the “Anglo-French Hajj” lineage [18]) spread rapidly from Saudi Arabia to the sub-Saharan African meningitis belt, South Africa, and Europe during 2000–2003, but declined thereafter [19, 20], and reappeared again in sub-Saharan Africa after 2010 [21].

In parallel, since 2003, an increase in IMD caused by MenW cc11 has been observed in South America, particularly in Brazil, Argentina, and Chile [22–24]. Since 2009/2010, there has also been an increase in MenW cc11 cases in Europe, Australia, Canada, North America, Asia, as well as a persistence of this strain in South America. The incidence of MenW IMD increased in European countries between 2013 and 2017: the Netherlands, Germany, Spain, Sweden, Switzerland, and France [25]. Thus, recently, concomitant multifocal expansion of

MenW has been observed in several areas worldwide (America, Europe, Oceania, Asia, Africa). The relationship between this recent wave of expansion of IMD MenW cc11 and the “Anglo-French Hajj” lineage that was described in the 2000s was resolved using whole genome sequencing that allowed the description of two independent lineages: the “Anglo-French Hajj” lineage and the “South American/UK” lineage [18]. The Anglo-French Hajj lineage emerged in the 2000s with the Hajj epidemic. The “South American/UK” lineage emerged in South America and then spread rapidly to Europe and beyond [26]. This latter lineage quickly diversified and generated the “Original UK” sub-lineage in 2009 and the “UK 2013” sub-lineage which spread rapidly to other European countries from 2013 [18].

Although sepsis and/or meningitis are the most common manifestations of IMD, a high proportion of invasive MenW cases have been reported to include atypical (non-meningeal) clinical presentations, such as bacteremic pneumonia, septic arthritis, and myocarditis [27]. A recent systematic review found that atypical MenW IMD presentation included acute gastrointestinal (GI) symptoms, septic arthritis and bacteremic pneumonia or severe upper respiratory tract infection (mainly epiglottitis) as prevalent symptoms [28]. That review, however, focused the literature search on these specific symptoms and was limited to the PubMed database and atypical presentation. In this article, we widened the literature search across two databases using a wider range of symptoms, signs and manifestations for a more comprehensive assessment of serogroup W IMD clinical presentation.

METHODS

Search Strategy

A systematic search of PubMed and Embase was undertaken via the ProQuest interface on 17 June 2022 without date restrictions using the following combination of search terms: (((neisseria OR bacterial meningitis OR meningococcal infections[MeSH Terms]) OR

(meningococc*[Text Word] OR Neisseria[Text Word] OR meningitis[Text Word])) AND ((-meningococcus, serogroup W 135[MeSH Terms]) OR (Serogroup W[Text Word] OR group W[Text Word] OR MenW[Text Word])) AND (sepsis or septicemia or septic shock or meningococemia or arthritis or urethritis or pericarditis or GI or gastrointestinal or gastroenteritis or gastro-enteritis or septic arthritis or respiratory or epiglottitis or supraepiglottitis or abdominal or pain or confusion or agitation or cold symptom or fever or chill or pharyngitis or peritonitis or endocarditis or myocarditis or myopericarditis or (extra-meningeal and (articular or pericardial or ocular)) or painful urin* or arthralgia or myalgia or asthenia or abducens palsy or cerebellitis or cerebellar infarction or nausea or diarrhoea or diarrhea or vomiting or necrotizing fasciitis or petechiae or conjunctivitis or rash or purpura fulminans or acute renal failure or kidney failure or disseminated intravascular coagulation or “upper respiratory tract symptoms” or headache or neck stiffness).

Eligibility Criteria

We sought original articles published in English (or at least had an English abstract) describing the clinical manifestation of laboratory-confirmed (as defined by the studies: culture, PCR, whole genome sequencing, latex agglutination) invasive *N. meningitidis* serogroup W (MenW) disease. We excluded articles that presented no original clinical data or were immunogenicity, carriage, surveillance, risk factor, genomic, biochemical characterization, or survey studies without information about clinical presentation. Clinical trials and vaccine studies were also excluded. The reference lists of review papers identified in the initial electronic search were checked for other potentially relevant reports.

Initially, titles and abstracts of all citations identified were assessed as a first step to exclude those that did not meet the inclusion criteria. Articles where there was any doubt as to their relevance to the current review and those that met the predefined selection criteria were obtained and fully analyzed in a second step.

Those with appropriate data were retained, with no restriction on patient population, geographical location, study design, or sample size. Information of the clinical presentation of laboratory-confirmed invasive MenW disease were entered into a standardized data table; the data summarized included region, patients' age and sex, study design, MenW confirmation methods, number of patients and symptoms reported before treatment initiation, and clinical manifestations (including outcomes).

For the purpose of the current review, clinical manifestations were categorized as meningitis, sepsis, sepsis and meningitis, pneumonia (with meningococemia and with/without sepsis or meningitis), arthritis (with/without sepsis or meningitis), and other (with/without sepsis or meningitis). The definitions used for the manifestations differed between studies, and, as such, we utilized the definitions used within the studies identified without further modification. In general, meningitis was based on symptoms consistent with disease along with a positive cerebrospinal fluid culture/PCR, with or without positive blood culture/PCR. Similarly, sepsis was based on symptoms and a positive blood culture/PCR without a positive cerebrospinal fluid culture/PCR, although some studies did report this with meningitis [29]. Bacteremic pneumonia was based on symptoms in combination with positive blood culture/PCR. Other noninvasive diseases such as conjunctivitis, urethritis, epiglottitis, supraglottitis, or tonsillitis were only included if these were in conjunction with a positive blood culture/PCR. Arthritis was based on joint symptoms along with a positive joint fluid culture/PCR. The latter manifestations were categorized irrespective of sepsis or meningitis. This article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

Statistical Analyses

There were no additional statistical analyses undertaken beyond those reported in the original studies; the data were synthesized to

provide a narrative summary as the heterogeneity between studies precluded any meaningful statistical analyses.

RESULTS

Study Selection

Sixty-seven publications were selected for inclusion in the systematic review (Fig. 1), including four found from other sources [30–33]. Publication dates ranged from 1980 through to 2021 and included data from Africa ($n = 3$), Australasia ($n = 7$), East Asia ($n = 9$), Europe ($n = 39$), Middle East ($n = 2$), North America ($n = 4$), South America ($n = 2$), and Europe/Asia ($n = 1$). The study designs included (Supplementary Tables S1 and S2): single case ($n = 32$) [33–64], cases series (up to 10 cases) ($n = 11$) [65–75], hospital-based (including case series with > 10 cases) ($n = 7$) [76–82], or surveillance studies ($n = 17$) [29–32, 83–95]. Of the hospital-based or surveillance studies, six were prospective [77, 79, 80, 86, 87] or included a prospective component [83].

Age Affected Over Time

We assessed whether the age of MenW IMD cases reported had changed over time, by comparing ages of the cases reported in “old” and more recent publications. For the case studies (i.e., single case studies and studies that reported data for ≤ 10 cases), a scatterplot of the case age and year of publication shows the earliest cases reported from the 1980s were mainly adults, then from the 1990s through to 2010 cases were predominantly children and adolescents/young adults, and subsequently since 2010 cases were reported across all age groups (Fig. 2). We focused on single/small case studies because the ages of the cases are nearly always reported, the disease would have occurred at narrowly define time, and each case in the scatter plot would be of equal weight/relevance. Larger studies usually report data over a wider time period with the ages of the cases usually

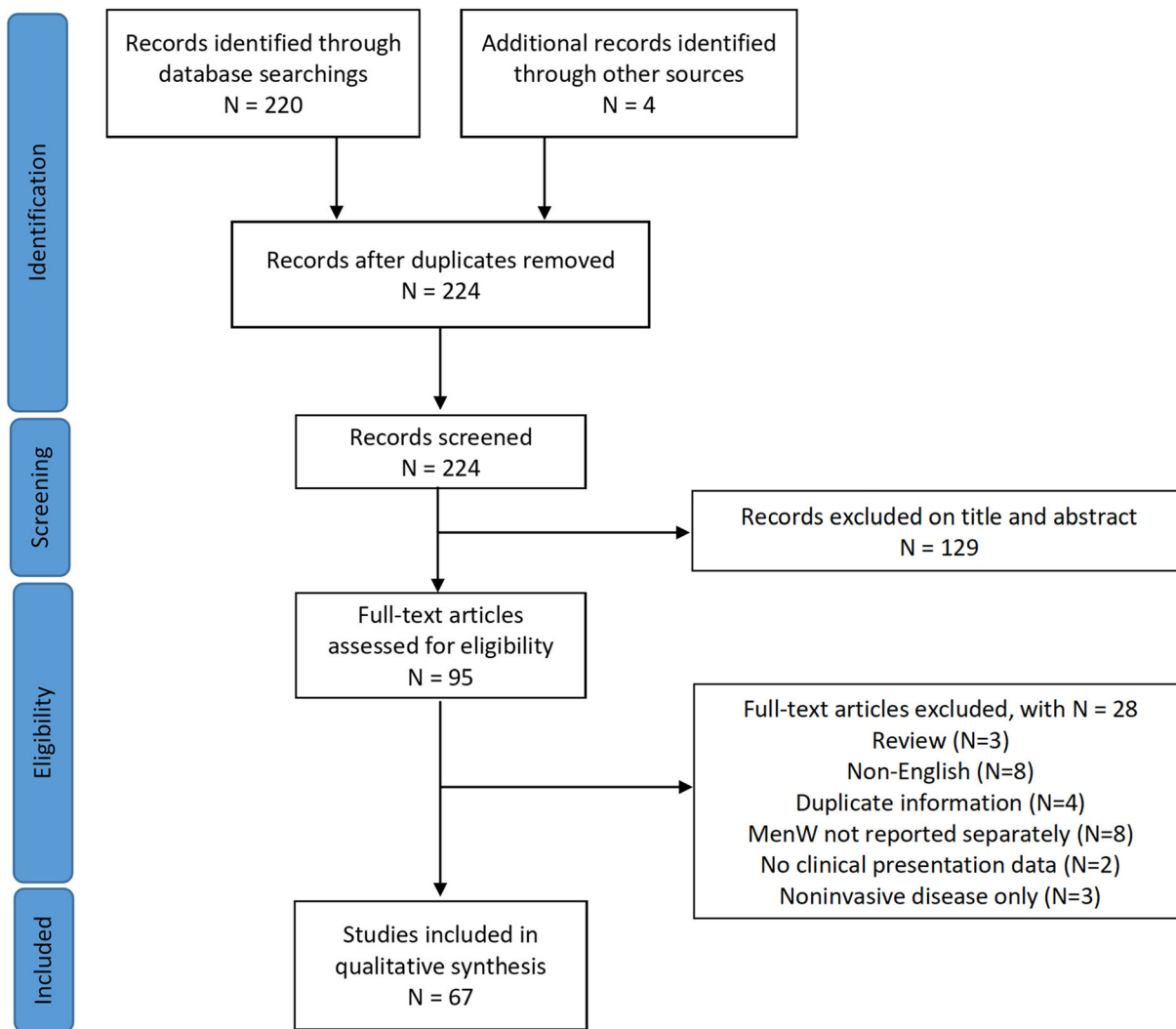


Fig. 1 PRISMA flowchart for the selection of articles included

aggregated, making identifying trends in the age of cases reported over time difficult.

Symptoms

The top ten common symptoms and signs reported among the studies that report symptomology for up to ten cases, encompassing 74 (28 female and 36 male; 10 with sex information missing) cases with confirmed MenW IMD, are summarized in Table 1. These included: fever, pain, vomiting, rash/spots, headache, diarrhea, altered consciousness/mental status,

cough, stiff neck, low blood pressure, and tachycardia.

Among the studies that report symptomology for > 10 cases, encompassing 3208 cases with confirmed MenW IMD, the top ten common symptoms and signs reported included (Table 2): fever, nausea and/or vomiting, vomiting, cough, sore throat, headache, diarrhea, altered consciousness/mental status, stiff neck, and nausea.

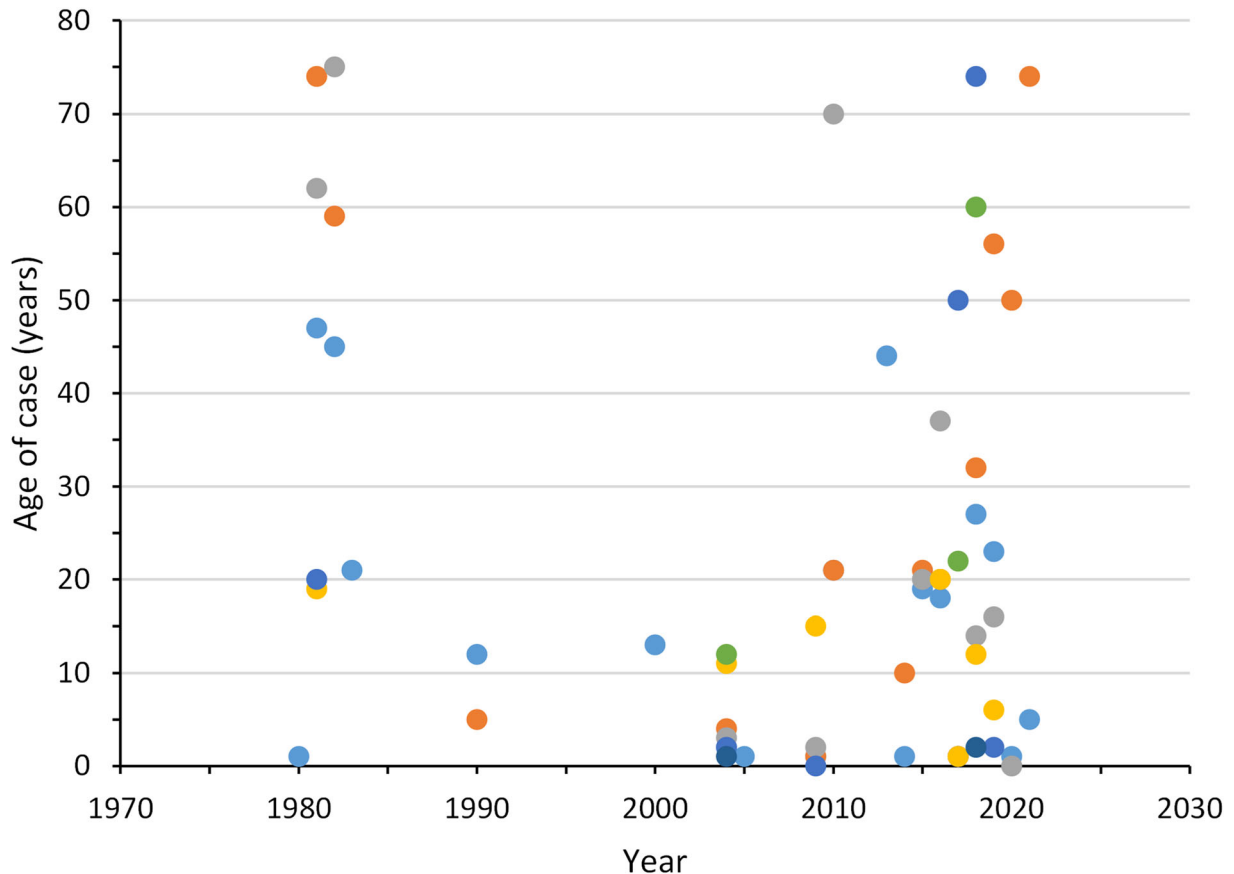


Fig. 2 Age affected over time: scatterplot of the case age and year of publication (single case studies or studies that reported data for ≤ 10 cases). Each dot represents an individual case

Clinical Manifestations

The main clinical manifestations among the studies that reported data for individual cases (up to ten cases) are summarized in Table 3. These included: sepsis, meningitis, sepsis and meningitis, arthritis, bacteremic pneumonia, and other. Of the 74 cases reported, 11 died.

The clinical manifestations among studies that reported data for > 10 cases are summarized in Table 4. These included: sepsis, meningitis, sepsis and meningitis, bacteremic pneumonia, arthritis, and other. The case fatality rates ranged from 8–40% [crude rate 15% (208/1382)] in studies that reported deaths, and among the survivors 4–14% [crude rate 9% (9/98)] had long-term sequelae (limb amputation, hearing loss, or neurological impairment) in studies that reported this outcome.

DISCUSSION

This review shows that the symptoms and signs of MenW IMD are nonspecific, regardless of whether the final clinical manifestation is sepsis, meningitis, or a combination of both. Moreover, the final clinical presentation may also include atypical manifestations. Commonly reported symptoms and signs of overt disease caused by MenW across the studies identified included fever, nausea and/or vomiting, cough, sore throat, diarrhea, headache, altered consciousness/mental status, and stiff neck.

Since IMD, irrespective of the causative serogroup, can rapidly progress to life-threatening illness, timely diagnosis is paramount but hampered by the nonspecific nature of the symptoms and signs. A retrospective UK

Table 1 Top ten symptoms reported by MenW IMD cases in studies that reported symptomology for up to 10 cases

Symptom	Number of cases (<i>n</i> = 74)	Source
Fever	42	[33, 35, 38–40, 42–45, 48–50, 52–54, 60, 61, 63, 65–68, 70–75]
Pain [#]	25	[33, 35–37, 39, 41–45, 47–50, 52, 55, 65, 68, 70, 73–75]
Vomiting	15	[33–36, 63, 65, 67, 68, 72–74]
Rash/spots [§]	12	[36, 38, 48, 56, 63–66, 70]
Headache	11	[33, 38, 47, 65, 66, 68, 72, 74]
Diarrhea	10	[34, 36, 43, 48, 67, 68, 73]
Altered consciousness/mental status	9	[38, 40, 49, 63, 65, 66, 68, 73]
Cough	8	[39, 42, 44, 66, 68, 73, 74]
Stiff neck	8	[38, 40, 65, 66, 68, 72, 73]
Low blood pressure	6	[34, 38, 43, 47, 68, 82]
Tachycardia	6	[34, 38, 40, 52, 66, 68]

[#]Includes chest, eye, leg/ankle, hip, knee, and abdomen pain

[§]Maculopapular/petechial/purpuric

Table 2 Top ten symptoms reported by MenW IMD cases among the studies that report symptomology for > 10 cases

Symptom	Crude rate, % (<i>n</i> / <i>M</i>)	Range	Source
Fever	79% (310/393)	36–100%	[77, 78, 80, 84, 87, 89, 90, 94]
Nausea and/or vomiting [#]	44% (36/81)	38–47%	[89, 90]
Vomiting [#]	35% (118/336)	14–68%	[76, 78, 80, 84, 87, 94]
Cough	28% (112/404)	7–57%	[76–78, 84, 87, 90]
Sore throat	26% (76/291)	13–34%	[76, 84, 87, 90]
Headache	25% (84/333)	7–50%	[76, 80, 84, 87, 90, 94]
Diarrhea	22% (81/368)	8–47%	[76, 78, 84, 87, 89, 94]
Altered consciousness/mental status	18% (52/291)	7–38%	[76, 84, 87, 90]
Stiff neck	18% (33/185)	7–54%	[76, 84, 87, 90]
Nausea [#]	18% (29/157)	7–20%	[84, 87]

Proportions shown are based on studies that reported these outcomes

n number of cases with the symptom, *M* number of cases in the studies that report the symptom

[#]Nausea and vomiting were reported separately or combined in some studies

Table 3 Clinical manifestations reported for MenW IMD cases among studies that report data for up to ten cases

Symptom	Number of cases (<i>n</i> = 74)	Source
Sepsis	27	[33–36, 41, 42, 47–49, 52, 56, 57, 59, 60, 64–66, 68, 70, 72, 73, 81, 82]
Meningitis	17	[63, 65–69, 71, 73, 81]
Sepsis and meningitis	4	[40, 66, 81]
Arthritis	10	[37, 39, 44, 50, 51, 53–55, 69]
Bacteremic pneumonia	4	[68, 75]
Other [#]	8	[38, 43, 45, 46, 58, 62, 74]

[#]Other manifestations include: pericarditis, myocarditis, bacteremic conjunctivitis

Table 4 Clinical manifestations reported for MenW IMD cases among the studies that reported data for > 10 cases

Symptom	Crude rate, % (<i>n</i> / <i>M</i>)	Range	Source
Sepsis	45% (669/1481)	15–83%	[29, 31, 76, 78, 79, 83, 84, 87–92, 95]
Meningitis [‡]	29% (419/1434)	5–72%	[29, 31, 76, 78–80, 83, 87, 88, 90–92, 95]
Sepsis and meningitis	17% (168/991)	6–74%	[29, 31, 79, 83, 84, 86–88, 91, 92]
Bacteremic pneumonia [§]	13% (109/850)	4–24%	[29, 30, 76, 78, 83–87, 90]
Arthritis [§]	5% (115/2460)	1–15%	[29, 30, 32, 76, 78, 83–88, 90, 95]
Other ^{#§}	11% (141/1328)	1–24%	[29–31, 76, 78, 80, 83–87, 91]

Proportions shown are based on studies that reported these manifestations and which reported all available IMD cases [i.e., excluding studies that only focused on those with a specific manifestation (e.g., excluding studies that focused on those with meningitis only [77, 86])]. Cases reported may have experienced more than one manifestation in some studies. As such, the proportions shown are not based on a common denominator (i.e., do not add up to 100%)

n, number of cases with the symptom; *M*, number of cases in the studies that report the symptom

[‡]With/without meningococemia

[§]Manifestation with/without sepsis or meningitis

[#]Other manifestations include: pharyngitis, epiglottitis, supraglottitis, tonsillitis, conjunctivitis, cellulitis, and pericarditis

analysis of a survey assessing the course of illness before hospital admission of children and adolescents (*n* = 448) with meningococcal disease found that about half were sent back home after the first consultation with their general practitioners (GPs) [96]. Similarly, a retrospective analysis of a French national public health insurance database assessing care pathways in IMD reported that in the three days prior to

hospital admission (*n* = 995), 28.2% had been sent home following a previous consultation with a physician [97]. Thus, delays seem inevitable unless the diagnostic value of the nonspecific symptoms and signs in identifying those with serious infections can be better ascertained to enable accurate assessment and timely management.

Among the studies identified that compared the clinical features of MenW disease with those caused by other meningococcal serogroups, a prospective analysis of IMD cases ($n = 565$) reported to the Dutch IMD surveillance system between 1 January 2015 and 30 June 2018 found that patients with MenW were more often diagnosed with septicemia/septic shock without meningitis (46%) and less often with meningitis without septicemia/septic shock (17%) than other serogroups [87]. Pneumonia (19%) or arthritis (12%) without septicemia or meningitis were highest in those with MenY and MenC IMD, respectively. Symptoms of petechiae and neck stiffness, were highest among MenB cases (38% and 33%, respectively) and relatively low among MenW (9% and 12%), and MenY (14% and 8%) IMD cases. However, both MenW and MenY cases more often had symptoms such as diarrhea (19% and 12%, respectively), as well as cough (19% and 14%), shortness of breath (18% and 17%), pain while breathing (5% and 8%), or a sore throat (21% and 14%) than MenB cases.

Similar results were reported in a retrospective analysis of epidemiologic data from the Taiwanese national surveillance system between 2001 and 2003 ($n = 115$) [90]: bacteremia without meningitis (52%) accounted for most MenW cases, although the remainder were meningitis (48%). Although sore throat and cough were the only symptoms reported more frequently with MenW cases than with the other serogroups, the differences were not statistically significant. However, a significantly higher prevalence of pneumonia was found in MenW cases. An analysis of MenB, MenW, and MenY surveillance data obtained in England during 2014 ($n = 340$) in those aged ≥ 5 years also showed that septicemia was more often a diagnoses for MenW cases (53%) compared with other the serogroups (versus 40% and 44%) [29]. In addition, gastrointestinal (which collectively included nausea, vomiting, diarrhea and abdominal pain; 30%) and upper respiratory tract (sore throat, cough, difficulty swallowing and swollen throat; 31%) symptoms were more likely to occur among MenW cases than the other serogroups.

An analysis of strains causing meningococcal septic arthritis cases ($n = 162$) in England and Wales between January 2010 and December 2020 showed that MenW was accountable for 40.9% (66/161) of such cases, but only a small proportion of all MenW cases (5.1%, 66/1291) were septic arthritis (versus 0.8% to 4.9% with other serogroups) [32]. In particular, MenW strains caused the majority (63.0%, 34/54) of septic arthritis cases among children and adolescents (≤ 19 years). Moreover, controlling for age group, regression analyses indicated that MenW was almost six times more likely to cause septic arthritis than MenB [odds ratio: 5.7; 95% confidence interval (CI) 3.7–8.7]. Similarly, MenY and MenC were four and five times more likely to cause septic arthritis than MenB (odds ratios 4.1 [CI 2.5–6.8] and 5.1 [CI 2.9–9.0], respectively). Thus, using MenB as a baseline, MenW appears to cause slightly more cases of septic arthritis than MenY and MenC, but this would need to be confirmed in more comprehensive studies; nonetheless, all these serogroups are more likely to cause septic arthritis than serogroup B.

Interestingly, anecdotal evidence of the ages of the MenW IMD cases reported appears to have changed over time since the earliest publications in 1980's. The first few initial cases reported were mainly adults, and subsequently reported mainly in children and adolescents/young adults from the 1990s through to 2010, and since 2010 across all age groups. The change in ages affected since 2010 appears generally consistent with the reported epidemiology of cases with the lineage "South American UK strain" in the Netherlands and UK, with the first few cases being mainly adults (2010–2012) and the elderly in particular, and then more cases among adolescents (10–19-year-olds in 2012–2013) and children < 5 years old after 2013 [98].

The main limitation of our review was related to the limited quality of included reports; these were predominately single-case/limited case series and retrospective studies. We cannot exclude the possibility of missing reports and incomplete/variable description of the symptoms across studies, or the possibility of double counting reported manifestations where

country surveillance data was presented across overlapping periods (or across studies). Another limitation was that only articles published in English or those that had an English abstract were considered. Inclusion of reports published in other languages may avoid potentially missing key information or introducing bias. Vaccination history of the reported cases was generally not reported and as such the impact of vaccination on symptom/severity profile in cases of breakthrough disease is unclear. In particular, quadrivalent meningococcal polysaccharide-conjugate vaccines (MenACWY) were introduced over a decade ago in some countries (targeting a wide age range), in part due to increase in MenW IMD cases [99], and as such, the symptoms and signs reported may differ in patients according to residual immunity after vaccination. Additionally, the assessment of symptomology/clinical features by MenW genotype was beyond the scope of the current review; it is possible that the clinical presentation may differ by MenW genotype encountered [100].

In conclusion, the clinical presentation of patients with MenW IMD is heterogeneous. Commonly reported symptoms included fever, vomiting, cough, headache, diarrhea, altered consciousness/mental status, and stiff neck, and are generally consistent with the typical IMD manifestations of sepsis and meningitis. Atypical manifestations such as pneumonia, arthritis, and other (e.g., pharyngitis, epiglottitis, supraglottitis, tonsillitis, conjunctivitis) constitute a sizable proportion of reported cases. Clinicians need to be aware of these atypical manifestations of IMD in regions where MenW is known to circulate to ensure timely diagnoses, identification of pathogen, and treatment. Nonetheless, these results further emphasise the importance of disease prevention through timely vaccination with available meningococcal vaccines, given the nonspecific nature of the symptoms and signs of IMD, and the likelihood of treatment delay.

ACKNOWLEDGEMENTS

The authors thank Anirban Sanyal, MSc, PhD, for editorial assistance and manuscript coordination on behalf of Sanofi.

Author Contributions. I.B-G., L.F., and F.C. contributed to concept/design and data selection. R.E.G. contributed to data selection and acquisition. I.B-G., L.F., F.C., T.G., and M.K.T. contributed to the interpretation of the data. All authors critically reviewed the manuscript and approved the final version for submission.

Funding. This work was supported by Sanofi. The sponsor also funded the journal's rapid service fee.

Data Availability. All data generated or analyzed during this study are included in the published article (and its Supplementary Information files).

Declarations

Conflict of Interest. I.B-G., L.F., and F.C. are employees of Sanofi and may hold shares and/or stock options in the company. R.E.G. is an employee of inScience Communications, Springer Healthcare Ltd, UK, which was contracted by Sanofi to undertake the literature search and provide editorial assistance. M.K.T. performs contract work for the Institut Pasteur funded by GSK, Pfizer, and Sanofi, and has a patent (NZ630133A) with GSK "vaccines for serogroup X meningococcus" issued.

Ethical Approval. This article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

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