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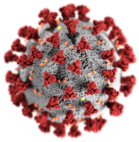
vACCine covid-19  monitoring readinESS

EVENT DEFINITION FORM

Event: **Guillain Barré Syndrome**
Outcome/covariate: outcome
Version: 1

Status: final

Contributing authors

authors	Role	Date
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Miriam Sturkenboom	Final codes	15-7-2021

1. Event definition

Brighton Collaboration definition

Guillain Barré syndrome is an immune-mediated disorder which can lead to autoimmune antibodies and/or inflammatory cells that cross react with components of peripheral nerves and roots, leading to demyelination or axonal damage or both. This results into various degrees of weakness, sensory abnormalities and autonomic dysfunction. The clinical findings patients with GBS present with are acute or subacute onset of varying degrees of weakness in limbs or cranial nerve-innervated muscles, associated with hypo –or areflexia and a characteristic profile in the cerebrospinal fluid (CSF).
The definition for Guillain Barré syndrome can be divided in different levels. These levels say something about the certainty of the diagnosis. [8]

Clinical case definitions: Guillain–Barré syndrome
Level 1 of diagnostic certainty
Bilateral AND flaccid weakness of the limbs [1,2]
AND
Decreased or absent deep tendon reflexes in weak limbs [3]
AND
Monophasic illness pattern [4] AND interval between onset and nadir of weakness between 12 h and 28 days AND subsequent clinical plateau [5]
AND
Electrophysiologic findings consistent with GBS [6]
*AND*Cytoalbuminologic dissociation (i.e., elevation of CSF protein level above laboratory normal value AND CSF total white cell count <50 cells/µl) [7]
AND
Absence of an identified alternative diagnosis for weakness (see Appendix A.3) [2]

Level 2 of diagnostic certainty
Bilateral AND flaccid weakness of the limbs [1,2]
AND
Decreased or absent deep tendon reflexes in weak limbs [3]
AND
Monophasic illness pattern [4] AND interval between onset and nadir of weakness between 12 h and 28 days AND subsequent clinical plateau [5]
AND
CSF total white cell count <50 cells/µl (with or without CSF protein elevation above laboratory normal value) [7]
OR
IF CSF not collected or results not available, electrophysiologic studies consistent with GBS [6]
AND
Absence of identified alternative diagnosis for weakness (see Appendix A.3) [2]

Level 3 of diagnostic certainty
Bilateral AND flaccid weakness of the limbs [1,2]
AND
Decreased or absent deep tendon reflexes in weak limbs [3]
AND
Monophasic illness pattern [4] AND interval between onset and nadir of weakness between 12 h and 28 days AND subsequent clinical plateau [5]
AND
Absence of identified alternative diagnosis for weakness (see Appendix A.3) [2]

These definitions do not apply for children under the 2 years, because their nervous system has not achieved the same level of development as in older children and adults. [8]

Appendix A.3 consists of the following diagnosis that has to be excluded before you can diagnose GBS: [2]
Intracranial
- Carcinomatous meningitis
- Brain stem encephalitis

Spinal cord
- Infarct, myelitis, compression
- Anterior horn cells of spinal cord
- Polio and other viruses producing poliomyelitis, including West Nile virus

Spinal nerve roots
- Chronic inflammatory demyelinating polyneuropathy
- Cauda equina compression

Peripheral nerves
- Metabolic derangements such as hypermagnesemia or hypophosphatemia
- Tic paralysis
- Heavy metal toxicity such as arsenic, gold and thallium
- Drug-induced neuropathy, (e.g., vincristine, platinum compounds, nitrofurantoin, paclitaxel)
- Porphyria
- Critical illness neuropathy
- Vasculitis
- Diphtheria

Neuromuscular junction
- Myasthenia gravis
- Organophosphate poisoning
- Botulism

Muscle
- Critical illness myopathy
- Polymyositis
- Dermatomyositis
- Hypo/hyperkalemia

GBS can be divided in different subtypes: Fisher syndrome (FS), acute inflammatory demyelinating polyradiculoneuropathy (AIDP), acute motor and sensory axonal neuropathy (AMSAN), acute motor axonal neuropathy (AMAN) and inexcitable. The definitions of these subtypes are the following:

Clinical case definitions: Fisher syndrome (FS)
Level 1 of diagnostic certainty
Bilateral ophthalmoparesis AND bilateral reduced or absent tendon reflexes, AND ataxia [9]
AND
Absence of limb weakness [10]
AND
Monophasic illness pattern AND interval between onset and nadir of weakness between 12 h and 28 days AND subsequent clinical plateau [11, 12]
AND
Cytoalbuminologic dissociation (i.e., elevation of cerebrospinal protein above the laboratory normal AND total CSF white cell count <50 cells/µl]) [13]
AND
Nerve conduction studies are normal, OR indicate involvement of sensory nerves only [14]
AND
No alterations in consciousness or corticospinal tract signs [15]

AND
Absence of identified alternative diagnosis [16]

Level 2 of diagnostic certainty
Bilateral ophthalmoparesis AND bilateral reduced or absent tendon reflexes AND ataxia [9]
AND
Absence of limb weakness [10]
AND
Monophasic illness pattern AND interval between onset and nadir of weakness between 12 h and 28 days AND subsequent clinical plateau [11, 12]
AND
Cerebrospinal fluid (CSF) with a total white cell count <50 cells/µl])[19] (with or without CSF protein elevation above laboratory normal value)
OR
Nerve conduction studies are normal, OR indicate involvement of sensory nerves only [14]
AND
No alterations in consciousness or corticospinal tract signs [15]
AND
Absence of identified alternative diagnosis [16]

Level 3 of diagnostic certainty
Bilateral ophthalmoparesis AND bilateral reduced or absent tendon reflexes AND ataxia [9]
AND
Absence of limb weakness [10]
AND
Monophasic illness pattern AND interval between onset and nadir of weakness between 12 h and 28 days AND subsequent clinical plateau. [11, 12]
AND
No alterations in consciousness or corticospinal tract signs [15]
AND
Absence of identified alternative diagnosis [16]

AIDP: [2]
At least one of the following in each of at least 2 nerves, or at least two of the following in one nerve if all others inexcitable and dCMAP (compound muscle action potential after distal stimulation) > 10% LLN:
1. Motor conduction velocity <90% LLN (lower limit of normal) (85% if dCMAP < 50% LLN).
2. Distal motor latency >110% ULN (>120% if dCMAP <100% LLN).
3. pCMAP (compound muscle action potential after proximal stimulation) /dCMAP ratio <0.5 and dCMAP >20% LLN.
4. F-response latency >120% ULN (upper limit of normal)

AMSAN: [2]
None of the features of AIDP except one demyelinating feature allowed in one nerve if dCMAP <10% LLN. Sensory action potential amplitudes <10% LLN.

AMAN: [2]
None of the features of AIDP except one demyelinating feature allowed in one nerve if dCMAP <10%LLN. Sensory action potential amplitudes normal.

Inexcitable: [2]
dCMAP absent in all nerves or present only in one nerve with dCMAP <10% LLN.

2. Synonyms / lay terms for the event

Synonyms for Guillain–Barré syndrome are the following: [8, 17]

- Fisher syndrome (FS)
- Acute motor and sensory axonal neuropathy (AMSAN)
- Acute motor axonal neuropathy (AMAN)
- Peripheral neuropathy
- Peripheral demyelination
- GBS
- Guillain Barre Syndrome
- Guillaine-Barre Syndrome
- Guillaine Barre Syndrome
- Guillain-Barré Syndrome
- Guillain Barré Syndrome
- Guillain-Barré Syndromes
- Landry-Guillain-Barre Syndrome
- Landry Guillain Barre Syndrome
- Acute Autoimmune Neuropathy
- Acute Autoimmune Neuropathies
- Acute Infectious Polyneuritis
- Acute polyneuritis
- Familial Guillain-Barre Syndrome
- Familial Guillain-Barre Syndromes
- Acute Inflammatory Demyelinating Polyneuropathy
- Acute Inflammatory Demyelinating Polyradiculoneuropathy
- AIDP
- Acute Inflammatory Polyneuropathy
- Acute Inflammatory Polyneuropathies
- Acute Inflammatory Polyradiculoneuropathies
- Acute Inflammatory Polyradiculoneuropathy

3. Laboratory tests that are specific for event

Blood Tests to exclude other diagnosis: sodium, potassium, phosphate, magnesium, liver enzymes, creatinine kinase, white blood cell count, C-reactive protein (on specific indication: thiamine, thyroid-stimulating hormone). [18]

Lumbar puncture is performed in patients with suspected GBS and especially to exclude other diagnoses rather than to confirm GBS. Specific for GBS is cytoalbuminologic dissociation. This is a combination of elevation of CSF protein level above laboratory normal value (reference range: 15-60 mg/dL) and CSF total white blood cell count (WBC) <50 cells/µl. [8, 18] To exclude other diagnosis also include the following, in addition to WBC and protein level:

- Red cell count (in cells/µl, normally there are no RBCs in CSF)
- Differential leukocyte count
    - Lymphocytes: normally 25% or more of total WBC count
    - Monocytes: normally 10% or less of total WBC count
    - Neutrophils: most abundant type of total WBC count
    - Eosinophils: normally 3% of total WBC count
- Glucose level (reference range: <50 mg/dL)
- Concomitant serum glucose level (reference range: <100 mg/dL after not eating).

Blood Serum for antiganglioside antibody detection can also be used for diagnosis. The different anti-gangliosides that can be detected in the different subtypes of GBS are as follows: [18]

- AIDP: various antibodies
- AMAN: GM1a, GM1b, GD1a and GaINAc-GD1a antibodies
- AMSAN: GM1, GD1a
- Fisher syndrome: GQ1b and GT1a antibodies

The antibodies are predominantly IgG, but IgM and IgA antibodies have also been demonstrated.

4. Diagnostic tests that are specific for event

Nerve conduction studies (NCS) and needle electromyography are used as diagnostic tests. The first detected NCS abnormalities are prolonged or absent F-waves. F waves are a late response that follows the motor response and is elicited by supramaximal electrical stimulation of a mixed or a motor nerve. [20] Abnormalities tend to peak >2 weeks after the onset of weakness. At least four motor nerves, three sensory nerves and F-waves should be investigated to increase the diagnostic yield of NCS. Abnormalities found on NCS depend on the GBS subtype: [8.18]

- AIDP features of demyelination, including prolonged distal motor latency, reduced nerve conduction velocity, prolonged F-wave latency, increased temporal dispersion and conduction block. The sural sensory potential is often preserved. [18,19]

- AMAN or AMSAN decreased motor and/or sensory amplitudes, typically in the absence of demyelinating features. [18,19]

5. Drugs that are used to treat event

Corticosteroids are not efficient to treat GBS or subtypes. [8,18]

6. Procedures used specific for event treatment

Indications for treatment are severely affected patients (inability to walk unaided, *GBS disability scale ≥3), especially when <2 weeks from onset of weakness. Also patients that are mildly affected (*GBS disability scale 1-2) surveillance for further deterioration/treatment indication receive the following procedure: [8, 18, 19]

- Intravenous immune globulin (IVIG): start within 2 weeks of onset: 0.4 g/kg daily for 5 days.
- Plasmapheresis start within 2-4 weeks with 5 x PE with a total exchange volume of five plasma volumes in 2 weeks.

If there is a secondary deterioration after initial improvement or stabilization, start with retreatment with IVIg or with PE.

* The GBS Disability Scale:

- 0: healthy
- 1: minor symptoms and capable of running
- 2: able to walk 10 meters without assistance but unable to run
- 3: able to walk 10 meters across an open space with help
- 4: bedridden or wheelchair-bound
- 5: requiring assisted ventilation for at least part of the day
- 6: dead

7. Setting (outpatient specialist, in-hospital, GP, emergency room) where condition will be most frequently /reliably diagnosed

The setting patients present themselves in are in-hospital or at the emergency room.

8. Diagnosis codes or algorithms used in different published reports/papers to extract the events in Europe/USA:

ICD-9-CM 357.0: Guillain Barre Syndrome
ICD-10-CM G.61.0: Guillain Barre Syndrome

VAESCO study (2009)

CUI	UMLS CONCEPT	RCD-GPRD	ICD10	ICD9CM	ICPC
C0018378	Guillain barre	F370.00, F370000, F370100	G61.0	357.0	N94.1
C0393799	Miller Fisher Syndrome	F370200		357.0	
C0456517	Subacute inflammatory demyelinating polyradiculoneuropathy	F370z00		357.8	
addition	Chronic inflammatory demyelinating polyneuritis			357,81	
addition	Guillain Barre syndrome				

Validation study Denmark (Levison LS, Thomsen RW, Christensen DH, Mellemkjær T, Sindrup SH, Andersen H. Guillain-Barré syndrome in Denmark: validation of diagnostic codes and a population-based nationwide study of the incidence in a 30-year period. Clin Epidemiol. 2019;11:275-283. Published 2019 Apr 18. doi:10.2147/CLEP.S199839

GBS: ICD-8: 354.00: Polyradiculitis acuta (21.7% of all the GBS diagnoses) and ICD-10: DG61.0: GBS (78.3% of all the GBS diag- noses) and restricted the population to those with the first GBS discharge diagnosis (N=3,357).

Table 1 Validity of ICD-codes for Guillain-Barré syndrome in the DNPR

Category	Total (N)	GBS (N)	Non-GBS (N)	PPV(%)	95% CI
All	425	356	69	83.8	80.0–87.0
Gender					
Males	240	204	36	85.0	79.9–89.0
Females	185	152	33	82.2	76.0–87.0
Year of diagnosis					
1987–1996	92	70	22	76.1	66.4–83.7
1997–2006	155	132	23	85.2	78.7–89.9
2007–2016	178	154	24	86.5	80.7–90.8
Age at diagnosis (years)					
16–39	134	106	28	79.1	71.5–85.1
40–64	182	152	30	83.5	77.4–88.2
≥65	109	98	11	90.0	82.8–94.3
Type of hospital					
General	157	128	29	81.5	74.7–86.8
University	268	228	40	85.1	80.3–88.8

Abbreviations: N, number of cases; GBS, Guillain-Barré syndrome; PPV, positive predictive value; CI, confidence interval.

9. Algorithms in prior studies

According to the Sentinel HOI review
Algorithm for GBS

Primary Observed or Derived Algorithm Inpatient, primary position

>= 1 ICD-9 code: 357.0

AND
Outpatient, any position

>= 1 ICD-9 code: 357.0

EXCLUDE
patients with the following in the 365 day baseline: Any claim type, any position
>= 1 ICD-9 code: 357.0 or 357.81

A literature review conducted by the Sentinel investigators produced 9 publications regarding algorithms or codes to identify Guillain-Barre syndrome. We cite from this report (see link above)

"The challenge of identifying Guillain-Barre syndrome (GBS) in administrative data can be summarized by the following factors: a non-specific ICD-9 code, coding commonly referring to rule-out diagnoses or sometimes to history of GBS, and the miscoding of chronic inflammatory demyelinating polyneuropathy (CIDP) as GBS. The ICD-9 code commonly used when coding for GBS, 357.0 [acute infective polyneuritis], has inconsistent test characteristics when used alone. For example, while a PRISM study published by Yih et al. reported that 357.0 used in all care settings had a very low PPV of 12%-16%,23 other studies examining the same code in all settings reported a PPV closer to 30%.24, 25 This variation may be attributable to distinct types of data being used in different systems (e.g., claims vs. electronic medical record). Studies examining the code 357.0 in inpatient settings reported PPVs for any-position inpatient diagnoses of 357.0 in the range of 30%-45%.26-28 When this definition is restricted to primary inpatient diagnosis codes only, PPVs increased to 68%-82%"

After synthesizing the evidence from the literature and expert opinion, for defining GBS the workgroup recommends the following as the primary recommendation: at least one principal inpatient ICD-9 code for 357.0 (if/when primary diagnosis is reliably available from Data Partners) followed by at least one outpatient ICD-9 code for 357.0 in any position, excluding persons with a diagnosis of GBS (357.0) or CIDP (357.81) in the 1-365 days prior to the hospitalization of interest, in any setting. As a secondary algorithm, the workgroup recommends one principal inpatient ICD-9 code for 357.0 for researchers who do not have access to outpatient records or who are looking for a simplified definition that does not involved excluding past diagnoses of GBS"

10. Codes used in ACCESS

Coding system	Code	Code name	Concept	Concept name	Algorithm
ICD10/CM	G61.0	Guillain-Barre syndrome	C0018378	Guillain-Barre Syndrome	Narrow
ICD9CM	357.0	Acute infective polyneuritis	C0018378	Guillain-Barre Syndrome	Narrow
ICPC	N94.01				Narrow
RCD2	F370.	Acute infective polyneuritis	C0018378	Guillain-Barre Syndrome	Narrow
RCD2	F3700	Guillain-Barre syndrome	C0018378	Guillain-Barre Syndrome	Narrow
RCD2	F370z	Acute infective polyneurit.NOS	C0018378	Guillain-Barre Syndrome	Narrow
RCD2	F3701	Postinfectious polyneuritis	C0018378	Guillain-Barre Syndrome	Narrow
RCD2	F3702	Miller-Fisher syndrome	C0393799	Miller Fisher Syndrome	Narrow
SCTSPA	40956001	síndrome de Guillain-Barré	C0018378	Guillain-Barre Syndrome	Narrow
SCTSPA	1767005	síndrome de Fisher	C0393799	Miller Fisher Syndrome	Narrow
SCTSPA	1767005	síndrome de Fisher	C0393799	Miller Fisher Syndrome	Narrow
SNOMEDCT_US	155082001	Guillain-Barre syndrome	C0018378	Guillain-Barre Syndrome	Narrow
SNOMEDCT_US	267707000	Guillain-Barre syndrome	C0018378	Guillain-Barre Syndrome	Narrow
SNOMEDCT_US	40956001	Guillain-Barré syndrome	C0018378	Guillain-Barre Syndrome	Narrow
SNOMEDCT_US	1767005	Fisher's syndrome	C0393799	Miller Fisher Syndrome	Narrow
SNOMEDCT_US	193175006	Miller-Fisher variant of Guillain-Barre syndrome	C0393799	Miller Fisher Syndrome	Narrow
SNOMEDCT_US	230548007	Miller-Fisher variant of Guillain-Barre syndrome	C0393799	Miller Fisher Syndrome	Narrow
SNOMEDCT_US	1767005	Fisher's syndrome	C0393799	Miller Fisher Syndrome	Narrow

SNOMEDCT_US	193175006	Miller-Fisher variant of Guillain-Barre syndrome	C0393799	Miller Fisher Syndrome	Narrow
SNOMEDCT_US	230548007	Miller-Fisher variant of Guillain-Barre syndrome	C0393799	Miller Fisher Syndrome	Narrow
SNOMEDCT_US	40956001	Guillain Barre syndrome			narrow
SNOMEDCT_US	129131007	Acute infective polyneuritis NOS			narrow
SNOMEDCT_US	193174005	Postinfectious polyneuritis			narrow

11. Algorithm for ACCESS

CUI	UMLS CONCEPT
C0018378	Guillain barre
C0393799	Miller Fisher Syndrome
C0456517	Subacute inflammatory demyelinating polyradiculoneuropathy
addition	Chronic inflammatory demyelinating polyneuritis
addition	Guillain Barre syndrome

Concept Set	Concept	Codes
GBS	Guillain-barré syndrome	ICD10: G61.0 ICD9: 357 READ: F370., F3700, F370z, F3701 ICPC: N94005
	Miller Fisher syndrome	ICD10: G61.0 READ: F3702 ICD9:-- ICPC: --

Broad algorithm:

- Concept set = (GBS) - Any of the codes in any provenance, no prior codes
- Index date: first occurrence of any of these concept sets

Narrow algorithm:

- Concept set = (GBS) - Any of the above codes from hospitalization (inpatient) & another mentioning in any other location (no prior codes)
- Index date: first occurrence of any of these concept sets

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