Supplementary Material 2. Delphi Rounds 1, 2 and 3

Table S1. Delphi Round 1

| Concept item to be included in the definition of MIGRAINE-ATTRIBUTED BURDEN | Results | Item Clarity |
|---|---|---|
| | Correspondence with concept of ‘burden’ | Item Clarity |
| | 1 = does not correspond | 1 = unclear |
| | 2 = relevant but not critical | 2 = needs revision |
| | 3 = directly corresponds (critical) | 3 = clear |
| | Score: % Participants | Score: % Participants |
| Overarching concept that is the summation of the negative consequences of the disease | 1: 12.5 | 1: 0 |
| | 2: 0 | 2: 12.5 |
| | 3: 87.5 | 3: 87.5 |
| | **2+3: 87.5 (>70%)** | |
| Two-tiered, occurring at the societal and individual level | 1: 0 | 1: 12.5 |
| | 2: 25.0 | 2: 25.0 |
| | 3: 75.0 | 3: 62.5 |
| | **2+3: 100 (>70%)** | |
| Societal burden is defined as population-level morbidity that results in organizational, community or region-specific losses | 1: 12.5  
2: 25.0  
3: 62.5  
2+3: 87.5 (>70%) | 1: 12.5  
2: 37.5  
3: 50.0 |
|---|---|---|
| Individual burden consists of three different components; impact (impact of disease on a range of life roles), impaired quality of life, and disability | 1: 12.5  
2: 0  
3: 87.5  
2+3: 87.5 (>70%) | 1: 0  
2: 12.5  
3: 87.5 |
| For burden, impact, impaired quality of life, and disability, the latter concepts are a more specific component of the previous | 1: 37.5  
2: 25.0  
3: 25.0  
(NR: 12.5)  
2+3: 50.0 (≤70%) | 1: 50.0  
2: 25.0  
3: 25.0 |
| Concept item to be included in the definition of MIGRAINE-ATTRIBUTED IMPACT | Correspondence with concept of ‘impact’ | 1 = does not correspond  
2 = relevant but not critical  
3 = directly corresponds (critical) | 1 = unclear  
2 = needs revision  
3 = clear |
|                                                                                                           | Score: % Participants | Score: % Participants |
|-----------------------------------------------------------------------------------------------------------|-----------------------|-----------------------|
| Individual- and societal-level consequences of the disease, that when negative are relevant to capturing disease burden | 1: 12.5               | 1: 0                  |
|                                                                                                           | 2: 12.5               | 2: 62.5               |
|                                                                                                           | 3: 75.0               | 3: 37.5               |
|                                                                                                           | 2+3: 87.5 (>70%)      |                       |
| Impact needs to be coupled with “on” to have meaning                                                   | 1: 0                  | 1: 0                  |
|                                                                                                           | 2: 12.5               | 2: 12.5               |
|                                                                                                           | 3: 87.5               | 3: 87.5               |
|                                                                                                           | 2+3: 100 (>70%)       |                       |
| The negative impact of migraine may include outcomes related to the individual                          | 1: 12.5               | 1: 25.0               |
|                                                                                                           | 2: 12.5               | 2: 0                  |
|                                                                                                           | 3: 75.0               | 3: 75.0               |
|                                                                                                           | 2+3: 87.5 (>70%)      |                       |
| Impact of migraine on various individual outcomes is often cumulative with implications on future outcomes | 1: 0                  | 1: 37.5               |
|                                                                                                           | 2: 12.5               | 2: 0                  |
|                                                                                                           | 3: 75.0               | 3: 62.5               |
| (NR: 12.5)                                                                                                |                       |                       |
|                                                                                                           | 2+3: 87.5 (>70%)      |                       |
| Outcomes are also influenced by a range of individual and environmental factors                          | 1: 12.5               | 1: 12.5               |
|                                                                                                           | 2: 12.5               | 2: 12.5               |
| Concept item to be included in the definition of MIGRAINE-ATTRIBUTED DISABILITY | Correspondence with concept of ‘disability’ | Item Clarity |
|---|---|---|
| 1 = does not correspond | 2 = relevant but not critical | 3 = directly corresponds (critical) |
| Score: % Participants | | Score: % Participants |
| Physical and mental health impairments * caused by the disease | 1: 12.5 | 1: 12.5 |
| 2: 12.5 | 2: 0 | 2: 0 |
| 3: 75.0 | 3: 87.5 | 3: 87.5 |
| 2+3: 87.5 (>70%) | | |
* Impairments that reduce or prevent one from functioning at the level needed to participate or complete in day-to-day activities as would be expected when in a state of full health

|   | 1: 0 | 2: 0 | 3: 100 | 2+3: 100 (>70%) |
|---|------|------|--------|-----------------|
|   | 1: 12.5 | 2: 0 | 3: 87.5 | 2+3: 100 (>70%) |

Consequences of functional impairment are influenced by a range of individual and environmental factors

|   | 1: 0 | 2: 12.5 | 3: 87.5 | 2+3: 100 (>70%) |
|---|------|---------|--------|-----------------|
|   | 1: 25.0 | 2: 0 | 3: 75.0 | 2+3: 100 (>70%) |

Physical and mental health impairments associated with migraine collectively may result in the full loss of functioning and the need for bedrest, for short (hours) or long periods of time (days)

|   | 1: 12.5 | 2: 25.0 | 3: 50.0 (NR: 12.5) | 2+3: 75.0 (>70%) |
|---|--------|---------|-------------------|-----------------|
|   | 1: 12.5 | 2: 0 | 3: 62.5 (NR: 25.0) | 2+3: 75.0 (>70%) |

Concept item to be included in the definition of MIGRAINE-IMPACTED QUALITY OF LIFE

|   | Correspondence with concept of ‘quality of life’ | Item Clarity |
|---|-------------------------------------------------|--------------|
|   | 1 = does not correspond | 1 = unclear |
|   | 2 = relevant but not critical | 2 = needs revision |
|   | 3 = directly corresponds (critical) | 3 = clear |
| Statement                                                                 | Score: % Participants | Score: % Participants |
|--------------------------------------------------------------------------|-----------------------|-----------------------|
| Refers to an individual’s assessment of the implications of disease on their general well-being and position in life | 1: 0                  | 1: 25.0               |
|                                                                          | 2: 12.5               | 2: 12.5               |
|                                                                          | 3: 87.5               | 3: 62.5               |
|                                                                          | **2+3: 100 (>70%)**   |                      |
| Encompasses an individual’s health state, functional status (physical, mental, social), and overall well-being; within the context of their individual perspectives † and disease status | 1: 0                  | 1: 12.5               |
|                                                                          | 2: 25.0               | 2: 12.5               |
|                                                                          | 3: 75.0               | 3: 75.0               |
|                                                                          | **2+3: 100 (>70%)**   |                      |
| Disability is a component of impaired quality of life                     | 1: 37.5               | 1: 12.5               |
|                                                                          | 2: 0                  | 2: 12.5               |
|                                                                          | 3: 62.5               | 3: 75.0               |
|                                                                          | **2+3: 62.5 (≤70%)**  |                      |
| Early onset of disease may distort individuals’ views on what a state of complete physical, mental, and social well-being would be; and their perceptions of position in life and well-being in the absence of disease | 1: 37.5               | 1: 25.0               |
|                                                                          | 2: 12.5               | 2: 12.5               |
|                                                                          | 3: 37.5               | 3: 50.0               |
|                                                                          | *(NR: 12.5)*          | *(NR: 12.5)*          |
|                                                                          | **2+3: 50.0 (≤70%)**  |                      |

NR = No Response
### Table S2. Delphi Round 2

| Proposed Definitions                                                                 | Agreement with the proposed definition, % Participants | Agreement with both individual and societal level acknowledgment in the definition, % Participants |
|-------------------------------------------------------------------------------------|--------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| Migraine-attributed burden: Overarching concept that is the summation of all negative consequences of the disease, occurring during and between migraine headache attacks. It can be expressed at the individual, interpersonal-social, and/or societal level. | 87.5                                                   | 100                                                                                              |
| Migraine-attributed impact: Negative influences of the disease on one or more specified outcomes, occurring during and between migraine headache attacks. It can be expressed at the individual, interpersonal-social, and/or societal level. | 87.5                                                   | 87.5                                                                                             |
| Migraine-attributed disability: Physical, cognitive, and mental health incapacities imposed by the disease symptoms, within the context of one’s environment, that reduce or prevent one from functioning at the level | 75.0                                                   | NA                                                                                               |
needed to participate in or complete day-to-day activities as would be expected when in a state of full health.

| Migraine-impacted quality of life: Refers to an individual’s subjective assessment of the negative effects of the disease on their general well-being and position in life. It reflects an individual’s health state, and functional status (physical, mental, social). | 87.5 | NA |

NA = Not Applicable
Table S3. Delphi Round 3

| Proposed definitions in Round 2 | Summary of points raised in Round 2 and discussed in open forum in Round 3 | Final 100% consensus definitions and detailed descriptions following revisions during Round 3 |
|---------------------------------|------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|
| Migraine-attributed burden:     | • It is an overarching concept but this is not part of the definition. | Definition: The summation of all negative consequences of the disease or its diagnosis. |
| Overarching concept that is the | • Negative consequences of the diagnosis may also contribute to migraine-attributed burden. | Detailed description: The negative consequences of the disease include those occurring during or between migraine attacks, some that are borne by others than those with the disease, some that are cumulative over time and some that outlast the currency of the disease. Some negative consequences for the person with the disease may arise from the diagnostic label rather than the disease itself. |
| summation of all negative       | • The current wording does not embrace elements of burden that fall on others, those that are cumulative, and those that outlast the currency of the disease. | Migraine-attributed burden is consequently expressed at individual, interpersonal-social, and societal levels. |
| consequences of the disease,   | • Because burden encompasses everything, it is, not can be, expressed at all levels. | |
| occurring during and between    | • Minor points regarding wording were raised. | |
| migraine headache attacks. It   |                                                                                   |                                                                                                                   |
| can be expressed at the         |                                                                                   |                                                                                                                   |
| individual, interpersonal-social, and/or societal level. |                                                                                   |                                                                                                                   |
| Migraine-attributed impact:     | • Migraine-attributed impact is largely, but may not be solely, negative.         | Definition: The effect of the disease, or its diagnosis, on a specified aspect of life, health or wellbeing. |
| Negative influences of the      |                                                                                   |                                                                                                                   |
| disease on one or more specified outcomes, |                                                                                   |                                                                                                                   |
occurring during and between migraine headache attacks. It can be expressed at the individual, interpersonal-social, and/or societal level.

- Effects of the diagnosis may also contribute to migraine-attributed impact.
- Use of ‘outcomes’ may be confusing, as this term may be associated with clinical trials. ‘Aspects’ may be a more suitable term.
- Specifying that aspects of life, health or wellbeing can be affected may be helpful.
- Specifying which aspects of life, health or wellbeing can be affected may be helpful.
- Use of ‘occurring during and between migraine headache attacks’ is not needed.
- Providing more detail on expression at the individual, interpersonal-social, and/or societal level may be helpful.
- Associations between separate impacts are highly likely.
- Impact may be transient, lasting and/or cumulative.
- Minor points regarding wording were raised.

Detailed description: The disease, or its diagnosis, may affect:
the life, health, capabilities, aspirations, opportunities, work and production, prosperity, position in life, recreation or general wellbeing of the person with the disease;
relationships with others and the attitudes of those around them towards the person with the disease;
and, when multiplied by numbers of people with the disease, social groups, community, or society more generally.

Migraine-attributed impact is a singular effect on any one of these. When there are effects on more than one, each is a separate impact, distinct from any other, although associations between them are highly likely.
Depending on its nature, migraine-attributed impact may be transient, lasting and/or cumulative.
| Migraine-attributed disability: Physical, cognitive, and mental health incapacities imposed by the disease symptoms, within the context of one’s environment, that reduce or prevent one from functioning at the level needed to participate in or complete day-to-day activities as would be expected when in a state of full health. | • It is not only the disease symptoms that impose disability.  
• The current wording does not capture the influence of individual as well as environmental factors.  
• Since it is specific to the individual, who may not otherwise be in ‘full health’, these words are incorrect.  
• Migraine-attributed disability is expressed at individual level. | Definition: Physical, cognitive and mental incapacities imposed by the disease.  
Detailed description: Physical, cognitive and mental incapacities imposed by the disease are influenced (moderated or exacerbated) by the individual’s personal characteristics and expressed in the context of that individual’s environment, hindering, impairing or preventing participation in or completion of day-to-day activities as would be expected if the individual were free of the disease.  
Migraine-attributed disability is expressed at individual level. |
|---|---|---|
| Migraine-impacted quality of life: Refers to an individual’s subjective assessment of the negative effects of the disease on their general well-being and position in life. It reflects an individual’s health state, and | • Quality of life is influenced by negative (or positive) effects of disease but is not defined in terms of those effects (or the individual’s assessment of them).  
• Quality of life is determined in important part by prospects as well as position in life. | Definition: The subjective assessment by a person with the disease of their general wellbeing, position and prospects in life.  
Detailed description: Subjective assessment by a person with the disease of their general wellbeing, position and prospects in life takes due account of all aspects of their |
| functional status (physical, mental, social). | • It is expressed at individual level but may be summarised across populations.  
• It has meaning only in comparison with normative values.  
• Minor points regarding wording were raised. | health (including the disease) and of their physical, mental and social functional abilities.  
Migraine-impacted quality of life is expressed at individual level but may be summarised across populations. In either case, it has meaning only in comparison with normative values of quality of life. |