

Preface to recalculating time burden

The original voluntary survey modules, which consist of 17 one-time surveys, are estimated to take approximately 85 minutes for a respondent to complete (Table 1).

Table 1. Part of the previously approved burden table (2019).

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Person with ALS/Registry	ALS Case Validation Questions	1,670	1	2/60	56
	ALS Case Registration Form	1,500	1	10/60	250
	Voluntary Survey Modules	750	1	85/60	1,063
	Disease Progression Survey*	750	3	5/60	188

Based on this previously estimated average time burden of 85 minutes for the 17 one-time survey questions, we have estimated the time burden for each question by evaluating each survey (Table 2).

Table 2. Number of questions in each survey evaluated for time burden estimation.

Survey module	Survey description	Number of questions ^a counted toward time burden evaluation	% of survey	Time to complete survey (min)
Survey1	Demographics	13	2.3%	1.94
Survey2	Occupation	9	1.6%	1.34
Survey3	Military	4	0.7%	0.60
Survey4	Smoking and alcohol	10	1.8%	1.49
Survey5	Physical activity	19	3.3%	2.83
Survey6	Family history of neurodegenerative disease	19	3.3%	2.83
Survey6b	Brother	9	1.6%	1.34
Survey6s	Sister	9	1.6%	1.34
Survey6c	Children	10	1.8%	1.49
Survey8	Lifetime residential	9	1.6%	1.34
Survey9	Environmental exposure	78	13.6%	11.59
Survey10	Personal environmental exposure	25	4.4%	3.72
Survey11	Occupational/Hobby exposure	80	14.0%	11.91
Survey12	Women's reproductive history	10	1.8%	1.49
Survey13	Caffeine consumption	35	6.1%	5.21
Survey14	Injuries	44	7.7%	6.55
Survey15	Health insurance	1	0.2%	0.15
Survey16	Open ended etiological questions	2	0.4%	0.30
Survey17	Clinical data and symptom onset	33	5.8%	4.91
Survey18	Sports history	153	26.8%	22.78
Total		572		85.00

^a Questions in each survey counted toward time burden estimation does not necessarily equate to the total number of questions in the survey.

According to **Table 2**, a total of 572 questions were counted toward time burden calculation. Based on the proportion of questions each survey contributes to the total time estimate, it can take as little as less than a minute to ~23 minutes for a respondent to complete the survey.

For the purpose of estimating time burden for each question, calculation is based on two assumptions:

- We assume each question is applicable to all respondents.
- We assume each question has same level of difficulty to respond, thus equal time burden.

There are also exceptions:

- A male respondent would not take Survey 12 (Women’s reproductive history), so his estimated total time burden would be less than a female respondent who selects to complete the survey.
- Any respondent who selects “Other” response by manually typing in the provided field would have greater estimated total time burden.

If a respondent would take an average of 85 minutes to complete 17 one-time survey modules, which consist of 572 questions, each question would take about 0.15 minutes.

Reorganization of 17 one-time survey modules, plus the Disease Progression module (Survey 7)

Newly structured survey format consists of an Essential Questionnaire (EQ) and four Follow-up Questions modules (Table 3). Questions from 17 one-time surveys deemed critical to capture at the time of Registry enrollment are selected for Essential Questionnaire while remaining questions were further examined and classified into one of four categories as Follow-up Questions. Several questions were tagged as “Miscellaneous” and omitted from classification due to duplicate status (i.e. asked elsewhere during registration).

In addition, the respondents are also asked to complete the first of 3 longitudinal assessments of ALS-related functional status (Disease Progression module) at the time of registry enrollment.

Table 3. Reorganization of original surveys into different categories of Follow-up Questions modules

Appendix	Description and reorganization	Number of questions	Estimated burden (minutes)
E1	Essential Questionnaire Select questions from Surveys 1-18, excluding Survey 7 Survey16 Open ended etiological questions	111	16.65
E2	Disease Progression module Survey7 (First of three in Year 1 is administered after the Essential Questionnaire)		
E3	Follow-up Questions - Demography Survey1 Demographics Survey12 Women’s reproductive history	10	1.5
E4	Follow-up Questions - Lifestyle Factors Survey4 Smoking and alcohol Survey5 Physical activity Survey13 Caffeine consumption	241	36.15
E5	Follow-up Questions - Environmental Factors Survey2 Occupation Survey3 Military Survey8 Lifetime residential Survey9 Environmental exposure Survey10 Personal environmental exposure Survey11 Occupational/Hobby exposure	159	23.85

	Survey14	Injuries		
	Survey18	Sports history		
E6	Follow-up Questions - ALS-associated and Clinical Factors		47	7.05
	Survey6	Family history of neurodegenerative disease		
	Survey6b	Brother		
	Survey6s	Sister		
	Survey6c	Children		
	Survey15	Health insurance		
	Survey17	Clinical data and symptom onset		
	<i>Miscellaneous</i>		4	0.6
	Total		572	85.8

Following the classification of each question in the original voluntary survey modules into the newly formatted categories, questions for each section were further re-evaluated.

Combination and simplification of questions

In the process, we have identified several stand-alone questions that can be combined and merged due to similarity in the topic of question and its wording and format (Figure 1).

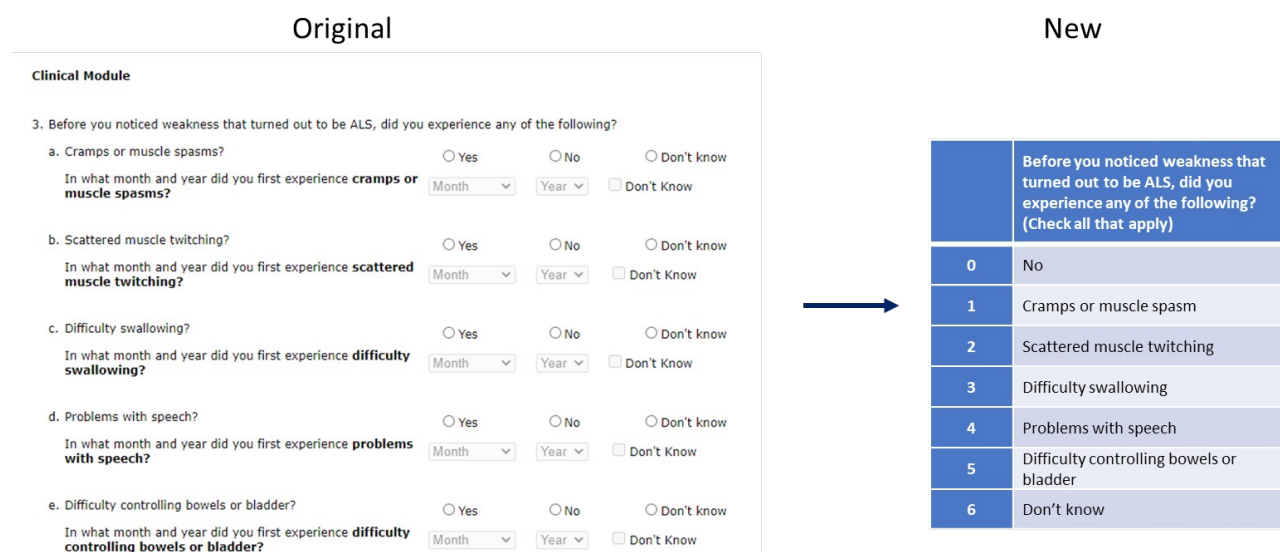


Figure 1. Example of question combination and simplification from the “original” to “new” to ease respondent's time burden to provide response.

For this assessment, we have reviewed questions in the new categories and identified whether they were eligible for merging (Table 4). Merging of eligible questions reduced number of questions in EQ and 2 of 4 Follow-up Questionnaire modules and decreased estimated time burden. In addition to the questions omitted from the classification due to duplicate status, there were several questions in EQ and Follow-up Questions: Environmental Factors where the responses are auto-filled due to reformat (further explained below), thus resulting in further reduction to the overall time burden estimate.

Table 4. Number of items from one-time surveys combined and merged to reduce estimated time burden in newly formatted survey structure

Form name	No. of Questions from the original modules	Estimated time as it stands without reformatting (minutes)	No. of Questions eligible for combination	No. of Questions merged	Time saved from combining questions (minutes) ^a
Essential Questionnaire	111	16.65	90	70	10.5
Follow-up Questions - Demography	10	1.5	0	0	0
Follow-up Questions - Lifestyle Factors	241	36.15	35	27	4.05
Follow-up Questions - Environmental Factors	159	23.85	8	4	0.6
Follow-up Questions - ALS-associated and Clinical Factors	47	7.05	0	0	0
Miscellaneous ^b	4	0.6	0	0	0
Total	572	85.8	133	101	15.15

^a Calculation: No. of questions merged x 0.15 minutes; Estimated time burden for each question is 0.15 minutes

^b Questions asked during registration, thus not categorized, and eliminated from EQ or the Followup Questions

Reducing unnecessary physical burden and effort

By simplifying the question format through combination and merge, certain responses are “auto-filled” in the new format, that’d otherwise require the respondent to manually select. Taking **Figure 1** as an example, by selecting [1. Cramps or muscle spasm] and [2. Scattered muscle twitching] in the new format, respondent is relieved from physically selecting “no” to other possible responses. Instead, the system will internally recognize the unselected response and will record “no”. This results in additional decrease in the estimated time burden (Table 5). At the end of completion of EQ or other modules, the respondent has a chance to review and correct the response if necessary.

Table 5. Number of auto-completed items in the new format that results in reduced estimated time burden

Form name	Questions auto-completed	Time saved (minutes) ^a
Essential Questionnaire	6	0.9
Disease progression module	0	0
Follow-up Questions - Demography	0	0
Follow-up Questions - Lifestyle Factors	0	0
Follow-up Questions - Environmental Factors	4	0.6
Follow-up Questions - ALS-associated and Clinical Factors	0	0
Total	10	1.5

^a Calculation: Number of auto-completed x 0.15 minutes; Estimated time burden for each question is 0.15 minutes

Collectively, restructuring the original volunteer survey modules into Essential Questionnaire and Follow-up Question modules, an estimated average time burden per respondent is reduced by 17.25 minutes (Table 6).

Table 6. Total time saved in the newly organized survey format.

	Time saved per respondent (minutes)
Table 4 – Combination and merge	15.15
Table 5 – Auto-completion	1.5
Miscellaneous – Duplicate status	0.6
Total	17.25

Table 7. Recalculation of total burden (in hours) in a newly formatted survey structure.

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Person with ALS/Registry	ALS Case Validation Questions	1,670	1	2/60	56
	ALS Case Registration Form	1,500	1	10/60	250
	Essential Questionnaire	750	1	6/60	75
	Disease Progression Survey (1 st time)	750	1	5/60	63
	Disease Progression Survey (2 nd and 3 rd time)	750	2	5/60	125
	Follow-up Questions - Demography	750	1	2/60	25
	Follow-up Questions - Lifestyle Factors	750	1	32/60	400
	Follow-up Questions - Environmental Factors	750	1	23/60	288
	Follow-up Questions - ALS-associated and Clinical Factors	750	1	7/60	88
Total	EQ + 4 Follow-up Question modules				876

As a result, compared to the original volunteer survey that would have taken 85 minutes per respondent to complete, the newly structured format would take approximately 58 minutes. **Should 750 respondents take this newly formatted survey, the estimated total burden (in hours) would be 876 instead of 1,063. This is a reduction of 188 hours in the estimated time burden.**