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Epidemiology, risk factors for disease or disease progression

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COMPARISON OF TWO DIFFERENT APPROACHES TO INVOLVE PARTICIPANTS IN CONSECUTIVE ROUNDS OF A DELPHI CONSENSUS TECHNIQUE.

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Background: There is no guidance on which participants to invite to consecutive rounds of a Delphi exercise. There are two options: 1) Invite only participants that have completed the previous round for the consecutive round; 2) Invite every participant for all consecutive rounds irrespective of whether they have responded. It is unknown whether different invitation-procedures provide similar results.

Objectives: To investigate the effect of two different approaches to involve participants in consecutive rounds of a Delphi exercise on response rate and final outcome.

Methods: Patients with and experts in spondyloarthritis were invited to partake in a 3-round Delphi exercise to update a core outcome set. A randomised controlled study with 1:1 allocation to two experimental groups was built in, to compare two approaches of invitation. The 'all-rounds group' includes patients invited for each round independent of response to the previous round; the 'respondents group' includes patients invited for the next round only if they responded to the previous round. A 9-point Likert scale (1=not important; 9=critical) was used to score the importance of domains. Additionally, participants provided their six most important domains.

Results: The overall response rate after 3 rounds was lower in the 'respondents' compared to the 'all-rounds group' (46% vs. 61%) (table 1).

Table 1. Response rates per group per round of the Delphi exercise

	'Respondents group' (N=187)	'All-rounds group' (N=189)
Round 1	Invited: 187 Completed: 122 Response rate: 65%	Invited: 189 Completed: 110 Response rate: 58%
Round 2	Invited: 122 Completed: 95 [response rate (78%)] Overall response rate: 51%	Invited: 189 Completed: 105 Response rate: 56%
Round 3	Invited: 95 Completed: 86 [response rate (91%)] Overall response rate: 46%	Invited: 189 Completed: 116 Response rate: 61%

There was no difference in mean (standard deviation) scores between the 'respondents' and 'all-rounds' groups for any domain (figure 1).

Figure 1 Mean score (SD) per domain for the 'respondents group' (in grey) and 'all-rounds group' (in blue) from the round when the domain was selected (i.e. the last available scores).

After the final round, the 4 outcomes with the highest percentage of votes were identical between experimental groups, with only small differences in percentages between groups (table 2). The only difference in the 6 most important domains was selection of disease activity by the 'respondents group', whereas the 'all-rounds group' selected overall functioning & health, while these domains were ranked as the 7th domain in the other group.

Table 2. Most important domains after round 3 for the 'respondents' and 'all-rounds' groups ranked in descending order, based on selection by the 'respondents' and matched in the 'all-rounds group'; and the difference in percentage of votes between groups. Domains in *italic* and bold represent the top 6 in each experimental group.

'Respondents group' N=86	'All-rounds group' N=116		Difference between groups		
Pain	95%	Pain	91%	Pain	4%
Stiffness	62%	Stiffness	62%	Stiffness	0%
Physical functioning	62%	Physical functioning	61%	Physical functioning	1%
Mobility	59%	Mobility	54%	Mobility	5%
Disease activity	55%	Disease activity	49%	Disease activity	6%
Fatigue	50%	Fatigue	55%	Fatigue	-5%
Overall functioning & health	47%	Overall functioning & health	57%	Overall functioning & health	-10%
Extra-musculoskeletal manifestations	44%	Extra-musculoskeletal manifestations	45%	Extra-musculoskeletal manifestations	-1%
Peripheral manifestations	34%	Peripheral manifestations	44%	Peripheral manifestations	-10%
Sleep	30%	Sleep	26%	Sleep	4%
Work & Employment	21%	Work & Employment	23%	Work & Employment	-2%
Emotional functioning	16%	Emotional functioning	18%	Emotional functioning	-2%

Conclusion: Inviting persons for all rounds irrespective of a response to the previous round increases the generalisability, while the content of the outcome of a Delphi procedure is similar to using data of those persons who participate in all rounds only.

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Validation of outcome measures and biomarkers

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SERUM LEVELS OF IL-6 AND IL-8 IN ANKYLOSING SPONDYLITIS PATIENTS: ASSOCIATIONS WITH DISEASE ACTIVITY

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Background: Ankylosing spondylitis (AS) is a chronic inflammatory disease of the spine and sacroiliac joints characterized by new bone formation (syndesmophytes) and ankyloses. In AS cases, along with the damage to the musculoskeletal system, impairment of other organs and systems is often observed (uveitis, inflammatory bowel and heart diseases). Pro-inflammatory cytokines (TNF- α , IL-6, -17, -23, -21, -22, -31) and chemokines (IL-8) are key pathogenic markers in AS.

Objectives: The aims of the study were to determine the serum levels of IL-6 and IL-8 in AS and investigate their relationship with disease activity.

Methods: We studied 140 patients (pts) with AS fulfilled modified New York criteria (1984); (102M/38F); median and interquartile range (25th—75th percentile) of age 43.0; 35.0-51.0 years; disease duration 6.0; 4.0-12.0 years; BASDAI - 5.4; 4.1-6.6; ASDAS ESR - 3.6; 2.6-4.4; ASDAS CRP - 3.8; 2.7-4.5; 86% HLA-27 positive. In 50% of pts with AS, inflammatory bowel diseases (IBD) (Crohn's disease and ulcerative colitis) were diagnosed. The control group included 17 healthy donors (HC). The serum concentrations of IL-6 and IL-8 were detected by chemiluminescence immunoassay using IMMULATE 1000 analyzer (Siemens Healthcare Diagnostics, USA).

Results: AS pts had significantly higher serum level of IL-6 than HC (4.3; 0.1-8.0 pg/ml vs 2.3; 0.1-2.7 pg/ml, p < 0.006). The median concentration of IL-8 didn't differ