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Letter to the Editor | **Other**

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Patient global assessment in rheumatoid arthritis: general health and disease activity are not interchangeable

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Rheumatology key message

- General health and disease activity items are not interchangeable within the rheumatoid arthritis patient global assessment domain.

Dear Editor, There are numerous composite response criteria and clinical outcome measures for RA disease activity (DA). Most, though not all, contain the complete set of OMERACT core outcome domains (Supplementary Table S1) but there has been no guidance on how items in these domains should be framed and, in the case of the Patient global assessment (PGA) domain, no consistency on whether this refers to DA or general health (GH). Also, the PGA domain has often been left undefined or optional. Legacy RA DA and Flare patient-reported outcome measures (PROMs) have been developed in the absence of any consensus for the PGA domain. Across RADAI5 (and the foot-specific RADAI-F5), RADAI, RADAI-SF, PDAS2, PRO-CLARA, GAS, PAS, PAS-II, RAPID3, RAPID4, PROM-score, FLARE-RA and RA-FQ [1], it can again be seen that there is minimal agreement on which domains should be covered in these PROMs (Supplementary Table S2). For instance, within RADAI-5, one item refers to DA—'How active was your arthritis in the last six months?'—and another refers to GH—'How would you describe your general health today?'

A 2016 review of the literature on PGA in measuring DA in RA [2] did not provide a guide on whether to refer specifically to DA or GH. The authors described the results from the QUEST-RA study [3] and concluded: 'The choice between the two concepts will depend on the objective of the measurement of the PGA. The global health question gives more holistic information on patient status since it includes to a wider extent elements such as comorbidities and psychological distress. The disease activity-PGA is more in line with more objective measures of disease and assesses more closely the inflammatory burden'. It would therefore suggest that when looking to measure the construct of RA DA, any PGA item should be a DA domain item. Previous research has investigated this matter and suggested an equivalence between these different formulations of PGA items in established RA, but that a difference seems to exist in early RA [4]. This highlights the continued problem of uncertainty in how to measure the construct of RA DA. There needs to be a consensus on the framing and content of items for the PGA domain including instructions, recall periods and response options.

The results of our Rasch measurement theory analyses, undertaken as part of a process to determine the best items to use to measure the construct of RA DA from legacy RA DA PROMs [1], show that DA and GH domain items do not function together within the PGA domain, and are in fact two separate domains.

Principal component analyses (Table 1) of the PGA items from that study [1] using the full sample show that DA and GH domain items clearly load onto factors reflecting their individual domains, with no overlap. Correlations of these items (Table 1) are high, though generally DA domain items correlate better with each other and GH domain items also correlate better with each other.

In cognitive interviews, in which participants were asked about an item bank of 24 items including DA and GH domain items [5], there was a lack of understanding of a GH domain item and questions from participants about whether to include mental health in response to a GH domain item. Furthermore, participants indicated that GH was separate from their RA DA. Therefore, DA and GH domain items are not interchangeable

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Table 1 Spearman's correlation coefficients and principal components analyses.

			General health domain items				*Disease activity* domain items				
		PS2	**T04**	**R05**	**P01**	**C01**	**PS1**	**D01**	**A01**	**T01**	**Q03**
General health domain items	PS2		0.858	0.743	0.767	0.855	0.672	0.572	0.676	0.570	0.566
	T04			0.783	0.749	0.906	0.661	0.573	0.693	0.602	0.597
	R05				0.816	0.785	0.762	0.636	0.766	0.681	0.669
	P01					0.769	0.761	0.644	0.743	0.682	0.679
	C01						0.667	0.557	0.691	0.575	0.588
Disease activity domain items	PS1							0.782	0.894	0.792	0.783
	D01								0.742	0.863	0.856
	A01									0.759	0.749
	T01										0.913
	Q03										
Principal component analyses											
Using Spearman's correlation coefficient			Factor 1	Factor 2	Using polychoric correlation coefficients			Factor 1	Factor 2		
	General health domain items	PS2	−0.0242	0.9443		*General health* domain items	PS2	−0.0293	0.9473		
		T04	−0.0131	0.9545			T04	−0.0070	0.9495		
		R05	0.2748	0.6970			R05	0.2801	0.6937		
		P01	0.3349	0.6449			P01	0.3324	0.6549		
		C01	−0.0434	0.9790			C01	−0.0415	0.9767		
	Disease activity domain items	PS1	0.7185	0.2718		*Disease activity* domain items	PS1	0.7215	0.2668		
		D01	0.9590	−0.0475			D01	0.9585	−0.0467		
		A01	0.6427	0.3383			A01	0.6419	0.3405		
		T01	0.9644	−0.0209			T01	0.9627	−0.0179		
		Q03	0.9581	−0.0197			Q03	0.9564	−0.0180		

and only DA domain items should be used in the measurement of the construct of RA DA. This is in line with the suggestion from the previous literature review [2], that any PGA item should be a DA domain item when looking to measure RA DA.

Multiple RA DA PROMs contain a GH domain item: RADAI5 and RADAI-F5, PRO-CLARA, PAS and PAS-II, RAPID3 and RAPID4 and PROM-score (Supplementary Table S2). RADAI5 (as seen in the earlier example), RADAI-F5 and PROM-score contain both GH and DA domain items. Of those with DA domain items, only RADAI, RADAI-SF and PDAS2 do not also contain a GH domain item. A recent systematic review [6] showed that none of the legacy RA DA PROMs can be recommended for use according to COSMIN guidelines, and analyses of these PROMs [1] also suggest that they do not have sufficient evidence for their measurement properties. It is therefore reasonable to disregard the legacy RA DA PROMs, including those that use a GH domain item. Future RA DA PROM development should not plan to include GH domain items.

There needs to be more clarity and consensus on valid measures for assessing the PGA domain, and this must come from international organizations like OMERACT, ACR and EULAR. At present, no such consensus has been provided: it is hoped that this finding will promote the need for these organizations to provide a consensus.

Supplementary material

Supplementary material is available at *Rheumatology* online.

Data availability

Data are available upon reasonable request to the Centre for Trials Research https://www.cardiff.ac.uk/centre-for-trials-research/collaborate-with-us/data-requests by any qualified researchers who engage in rigorous, independent scientific research and will be provided following review and approval of a research proposal and Statistical Analysis Plan (SAP) and execution of a Data Sharing Agreement (DSA). All data relevant to the study are included in the article.

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