POS0271-HPR

PATIENT PERSPECTIVE ON A DRUG SAFETY MONITORING SYSTEM FOR IMMUNE-MEDIATED INFLAMMATORY DISEASES BASED ON PATIENT-REPORTED OUTCOMES

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Background: Patient-reported outcomes (PROs) on adverse drug reactions (ADRs) are increasingly used in cohort event monitoring (CEM) to obtain a better understanding of patient's real-world experience with drugs. Despite the leading role for patients, little is known about their perspectives on these monitoring systems.

Objectives: To obtain more insight in patients' perspectives on the perceived usefulness, ease of use and attitude toward using the Dutch Biologic Monitor (DBM), and their preferred design for a national drug safety monitoring system for immune-mediated inflammatory diseases (IMIDs).

Methods: We developed a cross-sectional open survey following the rationale of the Technology Acceptance Model to obtain insight in patients' perspectives on the DBM. The DBM is a pilot for a PRO-based drug safety monitoring system focused on ADRs attributed to biologics that are prescribed for IMIDs. This survey consisted of 20 categorical and 1 open-ended question. Seven categorical questions contained a text field for additional comments. Five-point Likert-type scales or multiple-choice questions were used to identify patients' preferences and perspectives. Patients were eligible for the survey if they were still enrolled in the DBM at the time of the survey opening and if they had completed at least one questionnaire of the DBM. Categorical questions were descriptively analyzed, whereas text fields were analyzed using theoretical thematic analysis.

Results: At the start of the survey a total of 1,225 patients had participated in the DBM. Approximately 70% had an inflammatory rheumatic disease. The survey was completed by 292 eligible respondents (response rate 44.8%). The respondents generally agreed that it was useful to participate in the DBM and would recommend it to their peers (Figure 1). The response burden of the bimonthly questionnaires was scored as 'low', irrespective of the presence of ADRs or education level (Table 1). A number of respondents suggested that the questionnaire frequency should be synchronized with the regular hospital visits or the administration schedule of the biologic. Moreover, questionnaires should be offered less frequent and preferably shortened in case of an unaltered situation or absence of ADRs. Half (49.0%) of the respondents was interested in sharing their questionnaires with a medical specialist, whereas a third (34.2%) advocated sharing the questionnaires with their pharmacist (Figure 1).

Table 1. Perceived response burden of the Dutch Biologic Monitor questionnaires. The average burden is calculated using a five-point Likert-type scale. Data is represented as the number of respondents (n).

			ADRs reported						Education level[a]			
	Overall (n = 292)		Yes (n = 225)		No (n = 54)		Do not know (n = 13)		Lower (n = 149)		Higher (n = 139)	
Burden	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
1: No burden	224	(76.7)	169	(75.1)	46	(85.2)	9	(69.2)	106	(71.1)	115	(82.7)
2: Low burden	58	(19.9)	48	(21.3)	7	(13.0)	3	(23.1)	36	(24.2)	22	(15.8)
3: Moderate burden	6	(2.1)	6	(2.7)	0	(0.0)	0	(0.0)	4	(2.7)	2	(1.4)
4: High burden	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
5: Very high burden	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
No opinion	4	(1.4)	2	(0.9)	1	(1.9)	1	(0.0)	3	(2.0)	0	(0.0)
Average burden	1.2		1.3		1.1		1.2		1.3		1.2	

[a]Missing: 4 respondents.

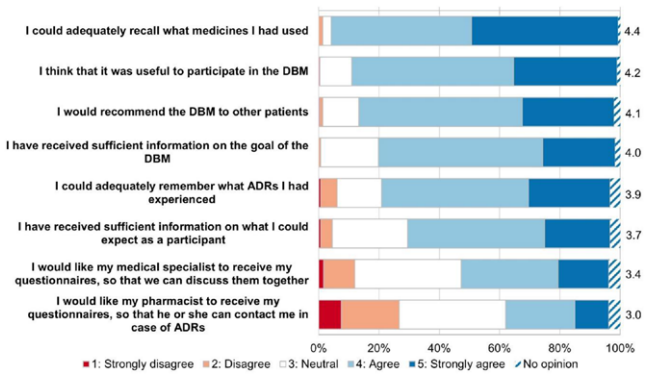

Figure 1. Stacked bar graph of user perspectives. Agreement scores were measured using a five-point Likert-type scale. The average agreement score per statement is indicated on the far right. The percentages represent the share of respondents. DBM: Dutch Biologic Monitor; ADRs: adverse drug reactions.

Conclusion: This study provides valuable insights in the patient perspective on a PRO-based drug safety monitoring system for inflammatory rheumatic diseases and other IMIDs, and provides several useful starting points to further stimulate and improve PRO-based CEM systems. Altogether, it appears feasible to establish a PRO-based drug safety monitoring system that monitors IMID patients' real-world experience with ADRs that has a low burden for the participants.

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POOR RESPONSE TO TKA: THE PERSPECTIVE OF PATIENTS AND KNEE SPECIALISTS

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