

A Systematic Review of Patient-Reported Outcome Measures and Validation Data Used in Melanoma Research and Clinical Practice



Jake R. Thompson,^{1,2} Tayla B. McCutcheon,^{1,2} Linda K. Martin,^{2,3} Robyn P.M. Saw,^{1,2,4} Iris Bartula,¹ Frances Boyle^{1,2,5}
1. Melanoma Institute Australia 2. The University of Sydney 3. University of New South Wales 4. Royal Prince Alfred Hospital 5. Mater Hospital



Background

Patient-reported outcome measures (PROMs) provide patients the opportunity to describe their symptoms and health-related quality of life (HRQoL), participate in shared-decision making, and generate valuable datasets on treatment effectiveness and adverse events.

As PROMs are increasingly used to guide melanoma research and clinical practice, the validation of commonly used PROMs for use in this population is unknown.

Objective

To synthesise the available PROMs that have been used in melanoma research and clinical practice, whilst identifying, and highlighting gaps in the available validation data to guide future research, psychometric analyses, and selection of PROMs for use in clinical practice or health services management

Methods

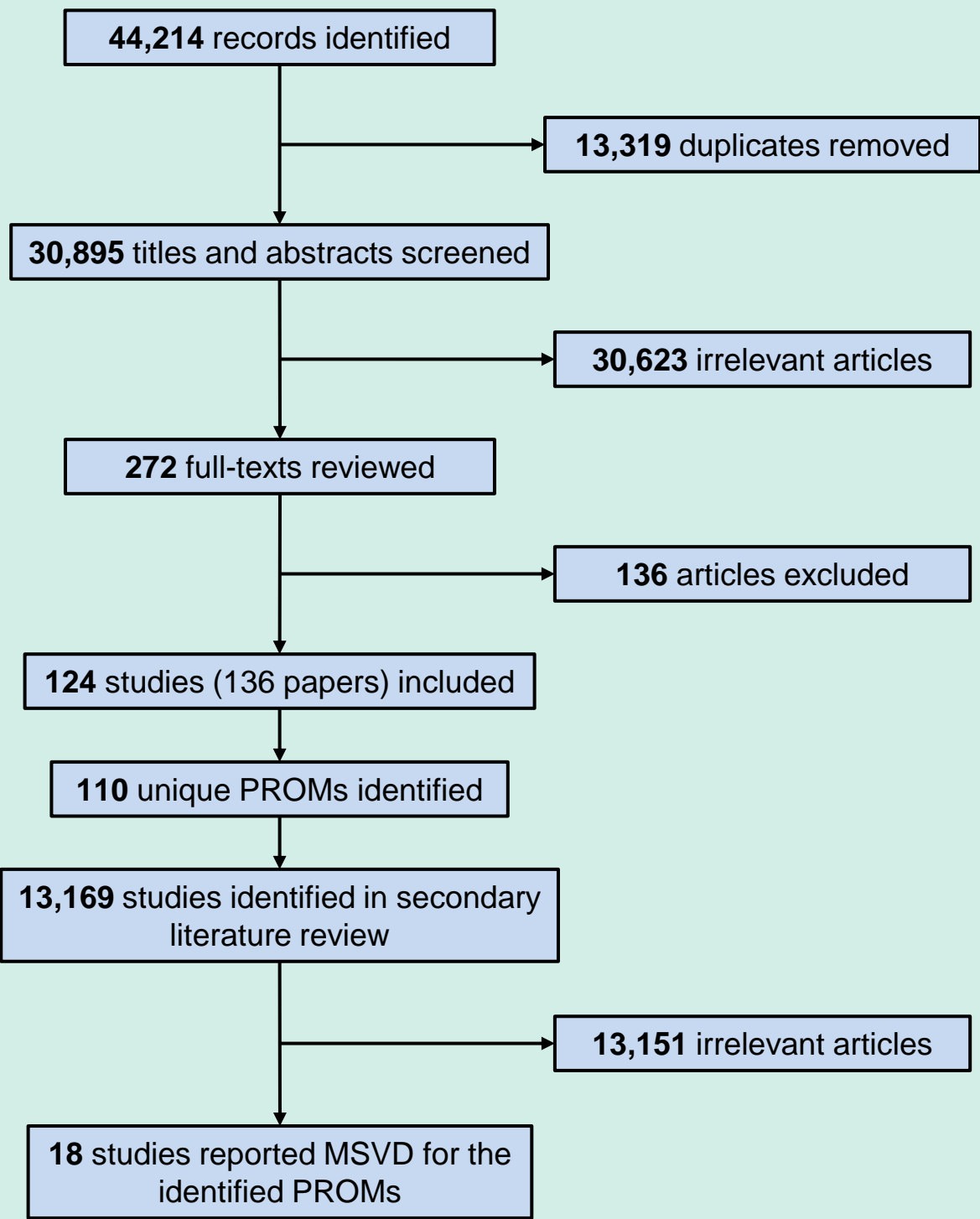
A systematic review was conducted in January 2025.

Inclusion criteria for the systematic review were:

- Any study that utilised a PROM to evaluate melanoma patient outcomes
- Studies published from January 1st, 2010, onward
- Cutaneous melanoma patients of any stage (stage 0-IV)
- Any type of study intervention (i.e., psychosocial, drug therapy)
- Any primary outcome measure (i.e., anxiety, adverse events, satisfaction)

Following the identification of PROMs used in melanoma research and clinical practice, secondary literature reviews were conducted to identify available melanoma-specific validation data (MSVD) for each identified PROM.

A validation score was then calculated for each PROM, with a point awarded for each of eight psychometric properties of interest where melanoma-specific data was available.



Flow Chart of Search Strategy Results

Results

Available Melanoma-Related Validation Data for Identified Patient-Reported Outcome Measures

Patient-Reported Outcome Measure	IC	TR	Con	Cri	Construct Conv	Div	FA	SC	Overall Score (/8)	
Adaptation Questionnaire	+	-	-	-	-	-	-	-	1	
Assessment of Quality of Life – 8 Dimensions	+	-	-	+	+	-	-	+	4	
Brief COPE Scale	+	-	+	-	-	-	+	-	3	
EORTC Melanoma Module (MEL-38)	-	-	+	-	-	+	+	-	3	++
EuroQol 5 Dimensions 3 Levels (EQ-5D-3L)	-	-	-	-	-	+	-	+	2	+
EuroQol 5 Dimensions 5 Levels (EQ-5D-5L)	-	-	-	-	+	+	-	+	3	-
FACT – Melanoma	++	+	+	++	++	+	++	++	8	
Fear of Cancer Recurrence Questionnaire – 7-item	+	+	+	-	-	-	+	-	4	
Fear of Cancer Recurrence Inventory	-	-	-	-	+	+	+	-	3	IC
Generalized Anxiety Disorder Questionnaire	+	-	-	-	-	+	-	-	2	TR
Melanoma Concerns Questionnaire*	+	+	+	-	+	-	+	+	6	Con
Mental Health Inventory	+	-	-	-	-	-	-	-	1	Cri
Multidimensional Fatigue Inventory	+	-	-	-	+	+	-	-	3	Conv
Patient Health Questionnaire – 9-item	+	-	-	-	-	+	-	-	2	Div
Perception of Appearance Scale	+	-	+	-	+	+	-	+	5	SC
Supportive Care Needs Survey – Melanoma Module	+	+	++	-	+	+	+	-	6	
Skin Cancer Index	+	-	-	-	+	+	+	-	4	
Available Data for Each Category (/17)	13	4	7	2	9	11	8	6		

Bold, the questionnaire had a passing score (i.e., $\geq 4 / 8$)
The Melanoma Concerns Questionnaire is a refinement of the EORTC Melanoma Module (MEL-38).
EORTC: European Organisation for the Research and Treatment of Cancer; FACT: Functional Assessment of Cancer Therapy; IDI-ILA: Insitituto Dermopatico Dell’ Immacolata – Italian Lymphedema Association Questionnaire.

Conclusions

There is a **high degree of heterogeneity** amongst PROMs used in melanoma research and clinical practice, with 110 PROMs identified from 124 included studies.

Of 110 unique PROMs, only 17 (15%) had MSVD available.

Of these 17 PROMs, only the Functional Assessment of Cancer Therapy – Melanoma (FACT-M) questionnaire had MSVD available for all 8 psychometric variables of interest.

Based on these findings, the following PROMs are recommended when measuring the following outcomes in melanoma patients:

- HRQoL:** the FACT-M or Melanoma Concerns Questionnaire
- Unmet needs:** The Supportive Care Needs Survey – Melanoma Module
- Self/body image:** The Perception of Appearance Scale
- Fear of cancer recurrence:** Fear of Cancer Recurrence 7-item short-form

