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**Preliminary validation of a questionnaire assessing psychological distress in caregivers of patients with malignant mesothelioma: Mesothelioma Psychological Distress Tool—Caregivers**

**This is the author's manuscript**

*Original Citation:*

*Availability:*

This version is available <http://hdl.handle.net/2318/1800824> since 2021-09-10T17:37:31Z

*Published version:*

DOI:10.1002/pon.5789

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## Original Article

### **Title: Preliminary validation study of a questionnaire evaluating the psychological distress of the caregivers of patients with malignant mesothelioma: Mesothelioma Psychological Distress Tool – Caregivers**

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**Acknowledgments:** We thank Angela Maria Allevi, Anna Maria Badiali, Carol Brentisci, Valentina Cacciarini, Barbara Dallari, Marina Di Geronimo, Paola Giuntoli, Cristina Palermo, Paola Pedulla, Sandro Sanna and Isabella Settele and Serena Villa for the administration of the questionnaires in Tuscany, Piedmont, Lombardy, and Lazio.

**Funding statements:** This work was partially founded by INAIL Research Plan 2016–2018 - P903, BRIC n. 59 and INAIL Research Plan 2019–2021 – P901.

**Ethics Statement:** The study involving was approved by the Internal Review Board for Psychological Research of University of Turin and Ethical Committee of the Azienda Ospedaliera SS Antonio e Biagio e Cesare Arrigo (AVPM-14/11/2014).

**Conflict of Interest statement for all authors:** The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

**A data availability statement:** The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

**Author contributions**

M.B., F.G. and A.G. design the study and managed the research process. M.B., F.G., E.M., C.M., E.C. and F.G. collect data. C.C., D.A. and F.G. performed statistical analyses. M.B., F.G., A.M., I.G.F and A.G. performed the literature review. M.B. and F.G. took primary responsibility for initial drafting and were responsible for subsequent collation of inputs and redrafting. All authors critically revised the manuscript and approved its final version. All authors have read and agreed to the published version of the manuscript.

**Abstract**

**Objective:** To develop a short, flexible, and comprehensive tool to measure the psychological distress in caregivers of malignant mesothelioma (MM) patients: Mesothelioma Psychological Distress Tool – Caregivers version (MPDT-C).

**Methods:** Based on systematic review of relevant literature, aspects connected to caregivers' distress were derived. Expert researchers/clinicians developed an “item pool” for each identified aspect. Content validity was assessed through multiple mixed-method approach. A multicentric study was conducted to explore the factorial structure of MPDT-C (47 item) through a Bayesian Factor Analysis.

**Results:** A Bayesian exploratory factor analysis revealed an underlying three-factor structure. Factors were labelled Secondary Traumatic Stress, Engage in Caring, and Meaningful Cognitive Restructuring. All scales showed sufficient reliability and corrected item-total correlations. Women scored higher than men in Engage in Caring.

**Conclusion:** Taking care of MM patients is a stressful event that influences the caregiver's physical, emotional, and social wellbeing. Our study offered preliminary evidence of the psychometric properties of MPDT-C, which needs replication. Results suggest MPDT-C is a reliable tool to detect the psychic distress of this traumatized population.

**Keywords:** Asbestos, Caregivers, Malignant Mesothelioma, Cancer, Methods, Oncology, Psychological stress, Tool

## **Main Text**

### **Background**

Studies on the mental health of the caregivers of malignant mesothelioma (MM) patients are scarce.<sup>1</sup> The personal experience of caregivers seems to be rarely considered compared with that of MM patients,<sup>2</sup> and there is need for research exploring the experiences of this specific population.<sup>3</sup> Clinically, with its high symptom burden, incurability, rarity and mostly occupational-industrial causation, MM has a unique psychosocial impact.<sup>4</sup> This unique combination is central in understanding the psychological distress related to MM<sup>5-7</sup>

Often, family members became involved in the care process of the ill relative experiencing emotional reactions comparable with those experienced by the patient.<sup>8</sup> Managing the care needs and the high symptom burden of patients lead to several negative consequences in caregivers' lives.<sup>1</sup> Moreover, the lack of effective treatments and the "bad news" received in the communicative-relational processes have a traumatic impact<sup>1</sup> and expose them to intense feelings of inefficacy and helplessness.<sup>8</sup>

Under these circumstances, caregivers could find hard handling their own personal needs and to build up a psychological representation of what is happening to them and what they are going to face in the course of the disease.<sup>5</sup>

Some authors have found clinically higher levels of somatic and cognitive complaints, anxiety-depressive symptoms, and post-traumatic conditions in caregivers respect to MM patients, suggesting that the psychological sequelae of MM could be even more traumatic for them.<sup>9</sup> These experiences represent a traumatic reality difficult to handle where their need to be supported often remain unseen.<sup>10</sup>

The literature has repeatedly highlighted the importance of assessing the psychological needs of the caregivers of MM patients.<sup>1</sup> However, even if there is a large literature on caregivers' distress, validated tools for providing evidence of the peculiar psychological distress of the caregivers of MM patients are lacking.<sup>11</sup>

The aim of this study is to develop a brief self-reported questionnaire to evaluate the psychological distress of this population.

## **Material and methods**

### *Materials and development of the questionnaire*

Differently to the mainstream approach to test validation, there is a growing well recognized body of psychometric literature that give centrality on the test construction phase questioning on how theoretical attributes are structured, how observables are related to them, and what the functional form of that relation.<sup>12</sup> We followed reflective latent variable modelling scheme in which auxiliary and substantive theories are developed jointly to enhance our understanding of relationship among theoretical constructs and the mapping of these constructs onto the empirical world.<sup>13</sup>

Based on systematic review of relevant literature<sup>4</sup>, aspects connected to caregivers' distress were derived. Results were analysed by a group of 6 expert researchers and clinicians to understand how theoretical attributes are structured and possibly related. This group developed an "item pool" for each identified aspect. The criteria for choosing the experts were clinical experience with patients and caregivers of at least 5 years and psychometric experience for the development of tests. The operationalization process led to the identifications of the following 12 dimensions: depression, anxiety, post-traumatic stress symptoms, anger, shame, guilt, functional coping, dysfunctional coping, signs of workload/burden, compassion fatigue, role conflict, and personal needs. The wording of the items was "tailored" to the specific

characteristics of the target population to make them as clear and readable as possible, and to minimize possible biases in the response process.<sup>14</sup> In order to increase the content validity of the items 2 focus groups were convened in Rome and Alessandria, and comprised a heterogeneous group of experts (n = 19; oncologists, occupational physicians, palliative physicians, nurses, psychologists, researchers, and expert interviewers of COR) and a group of participants from the target population (n = 8). The information collected led to the removal and editing of items considered to be unclear or poorly formulated. The Subject Matter Experts Methodology (SME) was used<sup>15</sup> to evaluate quantitatively the validity of the test content. Thirty-three experts were contacted by email or telephone (health personnel involved in the multidisciplinary management of the disease or personnel involved in the epidemiological surveillance network of MM). They were asked to rate the degree of relevance of each item on a three-point, Likert-type scale (1 = “not at all relevant”; 2 = “somehow relevant”; 3 = “very relevant”). Items with a score of  $\geq 2$  were included in the questionnaire. The refinement process led to a final pool of 47 items which were randomly set in the test to reduce proximity effect. The Mesothelioma Psychological Distress Tool – Caregivers version (MPDT-C) is reported in the Appendix.

#### *Participants and procedure*

Data were collected through a prospective observational multicentric study. Participants were recruited through the Italian National Mesothelioma Registry (Registro Nazionale dei Mesoteliomi – ReNaM), a national epidemiological surveillance system based on regional centers (Centri Operativi Regionali – COR) that searches for MM cases actively and investigates the modalities of asbestos exposure.<sup>16</sup> Seventeen interviewers of the involved COR (Tuscany, Piedmont, Lombardy, and Lazio) were trained by psychological staff (March–June 2018).

Participants were recruited from the ReNaM register<sup>16,17</sup> of the regions involved in the project, they were contacted by telephone to request adhering to the project and interviewed in person. Caregivers who gave their written consent were enrolled in the study and consecutively administered by MPDT-C. A separate form for collection of sociodemographic data and medical data was developed. The data were collected confidentially and treated in aggregate form. A total of 707 individuals were recruited and 144 of them decided to participate in our

### *Data analyses*

First, we computed the proportions of endorsement of each point of the answer scale to assess the item score distributions and the adequacy of the answer scale. Then, we used Bayesian exploratory factor analysis<sup>18</sup> (BEFA) to explore whether operationalization of the different dimensions of the psychological suffering of caregivers of patients with mesothelioma could be more parsimoniously explained by broader underlying factors. BEFA has been shown to be a principled method to perform factor analysis with (relatively) small sample sizes and ordered categorical indicators<sup>19</sup>, as it the case of this study. BEFA was run with the 'BayesFM' package in R.<sup>20</sup> This model is dedicated (i.e., each variable loads onto only one factor, hence there are no cross-loadings) and factors are allowed to correlate. The analysis also requires specifying a number of prior parameters (e.g., the maximum number of factors). Since this prior specification might impact the outcome of the analysis, we simulated plausible prior distributions using the functions in the 'BayesFM' package, based on the number of items ( $n = 47$ ) and a specified maximum number of latent factors (here we use 23, in order to keep over 2 the minimum number of manifest variables dedicated to each latent factor for identification). After finding an optimal BEFA solution, we used the method described by Geldhof et al.<sup>21</sup> to compute the reliability of scale as McDonald's omega.<sup>22</sup> Omega is a measure of composite reliability designed for congeneric scales, i.e., scales in which the items may vary in how



strongly they are related to the construct being measured that is considered appropriate when the raw scores of the items from a scale are summed up to yield a total score, and thus they are equally weighted<sup>21</sup>. Values over .65 and .80 can be considered as sufficient and optimal, respectively.<sup>23</sup> Omegas were computed using a multilevel Bayesian Confirmatory Factor Analysis (BCFA) approach for ordinal indicators, as implemented in Mplus.<sup>24</sup> Similarly, corrected item-total correlations were computed as multilevel Bayesian correlations between the item score and the total scale score once the item is dropped, and are a measure of discrimination, i.e., the ability of the item to discriminate between participants with different levels of the construct measured by the scale. We considered as adequate values larger than .20<sup>2, 25</sup>, with their posterior 89% credible interval including .30. Finally, we used Bayesian Linear Mixed Models (LMMs) to test the association of scale scores with background variables. For all analyses, we report the 89% credible intervals of the posterior distributions (i.e., the central portion of the posterior distribution that contains 89% of the probable values, given the observed data), which are recommended over the 95% intervals as they are more stable.<sup>26</sup>

## Results

All scale scores were endorsed at least once for each item, which supported the adequacy of the answer scale (Table 2).

The BEFA revealed a clear 3-factor solution (probability = .95), and factor loadings are reported in Table 2. Based on the content of the items (Appendix), we labelled the factors as: 1) Secondary Traumatic Stress (STS), 2) Engage in Caring (EC), 3) Meaningful Cognitive Restructuring (MCR). Note that, to prevent the loss of too many items due to relatively low factor loadings, here we adopted a more conservative cut-off (.15) than the more common .30 or .40, provided that the credible interval did not contain zero. This led to the removal of only

two items (Table 2). The correlations of Factor 1 with Factor 2 and Factor 3 were .57 (-.15, .84) and .06 (-.29, .79), respectively, while the correlation of Factor 2 with Factor 3 was .42 (.18, .66).

We then performed the item and reliability analysis. As reported in the right-hand part of Table 2, the omega of the three scales derived from the BEFA was either sufficient (Factor 2) or optimal (Factors 1 and 3), and all corrected item-total correlations were larger than .20 and their 89% posterior credible interval contained .30. These results suggested that the scales were reliable and the items adequately discriminated between higher and lower levels of the constructs.

The LMMs revealed that the only relevant predictor of the scale scores was participant's sex for Engage in caring (females scoring higher than males), with a Bayes factor (BF) of 15.80 that suggested strong evidence for the effect<sup>27</sup> ( $10 < \text{BF} < 30$ ) (Supplementary Materials).

## **Discussion**

The main aim of the paper was to develop a specific short measure to assess the psychological distress of the caregivers of MM. The BEFA shows a robust 3-factor solution (STS, EC, MCR). STS is wide construct which could be conceptualized as the emotional and behavioral disruption which indirectly affects subjects exposed to others' traumatic experiences. Clinically, STS implies a constellation of reactions characterized as compassion fatigue and PTSD-like symptoms.<sup>28</sup> This clinical perspective – which assume that a repeated or extreme secondary exposure to trauma may lead to post-traumatic conditions as well – is in line with diagnostic criteria for PTSD defined in the Diagnostic and Statistical Manual, Fifth Edition (DSM–5).<sup>29</sup> According with Sprang<sup>30</sup> et al., these trauma-related adaptations may include altered emotions, beliefs, defensive behaviors, and altered states of consciousness. This

description is entirely covered by the items which loads on the Factor 1 which assess both emotional disturbances, negative beliefs, post-traumatic symptoms, the attempts to avoid and defend against both the intrusion of trauma memories and the danger of recurrences of traumatic events.<sup>30</sup> After MM diagnosis, usually family members necessitate to assume a significant caregiving role which implies significant changes in their identity, roles, and relationships, and relevant consequences for their physical, emotional, and social wellbeing.<sup>2,8</sup> All participants of our sample are family caregivers who are engaged in supporting MM patients' effective health management. Recently, it has been proposed a conceptual model to explain the multifaceted and processual experience of family caregiver engagement in healthcare: the Caregiving Health Engagement Model – CHE Model.<sup>31</sup> According with CHE Model the engagement of a family member in the care process dynamically changes on a continuum of 4 different profiles (i.e. denial, hyper-activation, drowning and balance) which represent different levels of involvement rooted in the subjective way the manage their own needs and the needs of the ill person respect to their new role of career.

Like the CHE Model, the second factor – EC – contain a wide range of items that seem to reflect different caregivers positions varying from the most dysfunctional and detached one to the more adaptive. Not surprisingly, in line with previous research,<sup>2,32,33</sup> our findings suggest a strong correlation between the degree of the engagement in caregiving and the severity of the indirect post-traumatic symptomatology. In line with previous studies which reveals that often caregivers of MM patients are wives and daughters,<sup>8,32</sup> probably because of the high incidence of MM in men and prevalently occupational origin of the disease,<sup>17</sup> women scored higher than men in EC.

The lack of effective treatments for MM along with the continuous and exhausting care and assistance provided expose caregivers to bereavement and several losses (i.e. loss of autonomy, loss of health, loss of vitality). In this kind of stressful and threatening situations human beings

face the difficult process to integrate autobiographical memories related to painful life events by cognitively reframing their personal experience.<sup>34</sup> This is mostly true in the case of mesothelioma where the largest amount of deaths are the legacy of the occupational exposure to asbestos and appear without any sense to family members.<sup>7</sup> Several items of the third factor (MCR) seem to reflect the caregivers attempt to cognitive restructuring their traumatic reality revealing their “need to structure relevant situations in meaningful, integrated ways” and “to understand and make reasonable the experiential world”.<sup>35</sup> Our previous research on caregivers’ narratives highlight a difficult process of assimilation of their traumatic reality into an existing coherent self-narrative<sup>2</sup> suggesting a crisis in meaning that simultaneously deprives the survivor of a significant past, a comprehensible present, and a purposeful future leading to possible complicated grief.<sup>36</sup> Clinically, the cognitive reconstruction of the sense of their personal life is also related to the transitions family members are going through, mostly related with their new role as caregivers and with the imminent death of their beloved ones. This relationship between the MM-related changes experienced by caregivers and their cognitive adaptational strategies to them is also supported by the strong correlation found between EC and MCR scales. The 3-factor structure found suggest that the psychic distress MM patients’ caregivers is related with the traumatic experience they lived liked to the disease and their role in caring.

### *Study limitations*

Our sample could be considered small with respect to common statistical guidelines, but it included a substantial proportion of the Italian population (20% of total MM cases in the regions of Italy involved in the project according to INAIL<sup>17</sup>). It also has to be noted that clinical research on traumatized populations is quite difficult to address and often implies working with small samples. For these reasons we have applied a Bayesian approach which provides a set of methodological tools and a broader philosophical framework particularly useful for studying

and understanding psychological trauma<sup>37</sup>. An another limitation may be to not have administered the questionnaire a second time to evaluate its stability/change over time, and other studies will be needed to do this. Someone could argue that the main limitation of this study is the lack of external-criterion validity assessment. Following Borsboom,<sup>38</sup> “psychological testing has a significant and direct impact on people’s lives” and “do not always stand on firm grounds”. Thus, before to apply inadequate representation of psychometric modeling it was crucial to develop a theoretical representation of the construct following a mixed clinical-conceptual and data-driven approach.

### *Clinical implications*

Our results shed lights into the theoretical conceptualization of an obscure clinically relevant phenomenon: the psychological distress of caregiver of MM patients. A key feature that emerge is that a trauma-centered perspective rather than a psychopathological approach could be more useful to understand the psychological pain of this population. Public health systems and policy makers should be aware of the vicarious traumatization experienced by them, offering multidisciplinary interventions which include listening offered by specialized psychologists.<sup>32,39,40</sup> Psychological interventions should be available throughout the path of the disease and after the death of the beloved ones, in order to help caregivers to handle the secondary traumatic stress and the burden of the care process, and to elaborate the grief.

### *Conclusions*

The paper offers a substantial improvement in the understanding and assessing the psychological distress in caregivers of MM patients. We developed a multidimensional short

and flexible measure able to help practitioners and researchers to detect the different nuances of the psychic pain of this population in order to tailor specific intervention.

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