Acta Biomed 2025; Vol. 96, N. 5: 17213 DOI: 10.23750/abm.v96i5.17213

Original article

Translation and socio-linguistic adaptation of the Maltese version of the decision regret scale

Alice Silvia Brera[1], Justin Lee Mifsud[2], Josef Trapani[2], Maria Cassar [2], Gianluca Conte[3], Arianna Magon[3], Silvia Belloni[4], Pier Mario Perrone[5], Silvana Castaldi[5,6], Cristina Arrigoni[4], Rosario Caruso[5]

[1]Department of Biomedicine and Prevention, University of Rome Tor Vergata, Rome, Italy; [2]Faculty of Health Sciences, Mater Dei Hospital, Msida, Malta; [3]Health Professions Research and Development Unit, IRCCS Policlinico San Donato, San Donato Milanese, Italy; [4]Department of Public Health, Experimental and Forensic Medicine, Section of Hygiene, University of Pavia, Pavia, Italy, [5]Department of Biomedical Sciences for Health, University of Milan, Milan, Italy; [6]Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy

Abstract. *Background and aim:* Decision regret (DR) is critical in patient-centred care, especially among individuals with chronic diseases who face complex healthcare decisions. Despite growing interest in DR as a measurable construct, no validated instrument exists in the Maltese language. This study aimed to translate the 5-item Decision Regret Scale (DRS) into Maltese and to evaluate its content validity, following a structured methodological approach. *Methods:* The study adopted a two-phase methodological design. In Phase One, the DRS was translated into Maltese using a collaborative and iterative model, as described by Douglas and Craig, which involved forward translation, synthesis, expert adjudication, and back-translation. Phase Two evaluated both quantitative and qualitative content validity. A panel of eight experts assessed the relevance and clarity of each item using the Content Validity Ratio (CVR), Item- and Scale-level Content Validity Indexes (I-CVI and S-CVI). Qualitative feedback was also collected to explore face validity and semantic nuances. *Results:* All items demonstrated acceptable CVR, I-CVI, and S-CVI values after two rounds of expert review. Items 3 and 5 required further discussion due to initial concerns about semantic overlap, resulting in the revision of item 3. Additionally, minor changes were introduced to enhance conceptual clarity. Final indices confirmed the content validity of all five items. *Conclusions:* The Maltese version of the DRS was found to be culturally appropriate, linguistically accurate, and content-valid. Further psychometric studies are recommended to assess construct validity, reliability, and responsiveness in clinical populations. (www.actabiomedica.it)

Key words: decision regret, patient-reported outcome measures, content validity, cross-cultural adaptation, non-communicable diseases, Maltese version

Introduction

Chronic diseases represent the leading cause of adult mortality and morbidity, accounting for more than 43 million deaths in 2021, approximately 75% of all non-pandemic-related deaths (1,2). The four major groups of chronic diseases, which are cardiovascular diseases, cancers, chronic respiratory diseases, and diabetes, collectively contribute to over 80% of premature chronic disease-related deaths worldwide (3,4). Additionally, mental health disorders are increasingly recognised as significant contributors to the global burden of chronic diseases, particularly in terms of economic and social costs (5). In Europe, nearly three-quarters

of chronic disease-related deaths occur, and individuals are disproportionately affected by premature mortality, with 18 million people dying before the age of 70 (6–8). Risk factors for developing and poorly managing chronic diseases are broadly categorised into modifiable and non-modifiable determinants (9). Modifiable factors, such as poor diet, physical inactivity, tobacco use, and harmful alcohol consumption, could be targeted through behavioural and public health interventions (10). In contrast, non-modifiable factors, such as age, sex, and genetic predisposition, necessitate early detection and tailored clinical pathways (11). In Malta, the burden of chronic diseases is increasing. Although life expectancy at birth remains among the highest in the European Union (EU), health disparities persist across socioeconomic and gender lines (12). A behaviorally related risk factor, such as obesity, is highly prevalent, and this is explainable by the high prevalence of low levels of physical activity and poor diet among the Maltese population (13,14). Malta has the highest adult obesity rate in the EU, and physical inactivity affects both adults and adolescents, particularly young females (15). Ischaemic heart disease remains the leading cause of avoidable mortality, followed by cancer, further emphasising the urgent need for effective prevention and management strategies (16). In the context of chronic diseases, clinical decision-making often involves complex scenarios where multiple treatment options are available. In such cases, the active engagement of patients is essential (17). Shared decision-making (SDM) frameworks advocate for the inclusion of patients as central participants in their care plans, yet in practice, patient voices are often underrepresented or overlooked (18). When patients are excluded from the decision-making process, they may later experience decision regret (DR) (19), which is defined as a psychological response characterised by dissatisfaction, disappointment, or self-blame related to health decisions made (18,20). DR is particularly relevant in chronic disease contexts, where treatment trajectories are prolonged, uncertain, and multidimensional (21). DR could manifest in several forms, including outcome regret (regret over the consequences), process regret (dissatisfaction with how the decision was made), or chosen option regret (regret about the selected alternative) (19,22,23). Factors such as limited health literacy, conflicting personal values, or insufficient professional support may exacerbate these experiences (21,24). Moreover, DR has been associated with poorer adherence, reduced quality of life, and increased psychological distress (25), especially when patients perceive that alternative decisions may have led to better outcomes (20,26). To reduce the incidence of DR, healthcare providers must adopt strategies that enhance patient-provider communication, facilitate the comprehension of medical information, and promote truly collaborative care processes. Understanding DR can also support the development of predictive models to identify at-risk individuals and tailor interventions accordingly (20,26). This is particularly important in vulnerable populations and resource-constrained settings, where the consequences of regret can extend to financial hardship and deteriorating clinical outcomes (27). Despite the growing recognition of DR as a critical component of patient-centred care evaluation, no validated instrument currently exists in the Maltese language to assess this construct. The Decision Regret Scale (DRS), originally developed by Brehaut et al. (28), is a widely used tool for evaluating patients' regret following health-related decisions. However, its use in Malta has been limited by the absence of a culturally and linguistically validated version. Establishing a valid and reliable version of the DRS for use in the Maltese context represents a foundational step for future research and clinical application, particularly in relation to chronic illness management and patient engagement in shared decision-making. For this reason, this study aimed to develop and validate a Maltese version of the DRS through a cultural adaptation and content validation process.

Methods

Design

This study followed a methodological design aimed at the cross-cultural adaptation and validation of the DRS in the Maltese language (Figure 1). The validation process was conducted in two sequential phases. The first phase focused on the cultural and linguistic validation of the scale, following

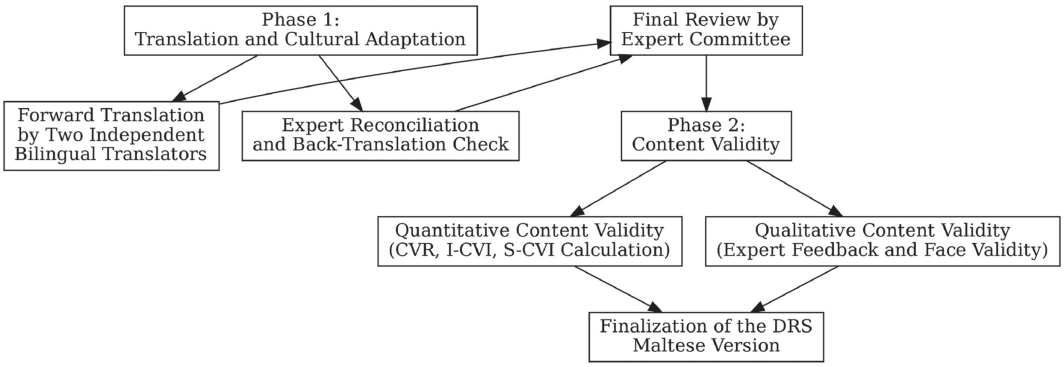

Figure 1. Overview of the study design and validation process. *Note:* The employed methodological framework adheres to COSMIN guidelines for evaluating content validity in the development and cross-cultural adaptation of patient-reported outcome measures.

established best practices for translation and adaptation of patient-reported outcome measures (29). The unidimensional structure of the original DRS was preserved throughout the translation and validation process to ensure conceptual equivalence. The second phase aimed to assess the content validity of the translated version through both quantitative and qualitative methods. Quantitative content validity was evaluated by computing the Content Validity Ratio (CVR), Item-level Content Validity Index (I-CVI), and Scale-level Content Validity Index (S-CVI) (30), as recommended by the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidelines (29). These indices were used to assess the relevance, clarity, and comprehensibility of the items. In parallel, qualitative content validity (i.e., face validity) was assessed by collecting open-ended feedback from experts to identify potential issues with item interpretation and conceptual alignment.

Decision regret scale

Decision regret has been assessed using various multi-item scales across disciplines (31–36). However, many of these instruments lack robust psychometric validation, particularly in terms of reliability and construct validity (33,35,36). Furthermore, several of these tools incorporate situation-specific items, which limit their generalizability. Most were originally developed in consumer behaviour or satisfaction research and tested in experimental settings rather than in real-world clinical contexts, thus reducing their applicability to healthcare decision-making (33–36). To address this gap, Brehaut et al. developed the DRS in English, which is a brief, validated, and generalisable instrument specifically designed to measure regret related to medical decisions (28). The DRS consists of five items rated on a 5-point Likert scale, ranging from 1 ("strongly agree") to 5 ("strongly disagree"). Respondents are asked to reflect on a specific health-related decision and indicate their level of agreement with each statement. The items evaluate dimensions such as whether the decision was appropriate, whether regret is felt, whether the individual would make the same choice again, whether the decision caused harm, and whether it was perceived as wise. To mitigate acquiescence bias, two of the items (items 2 and 4) are negatively worded (28). The five items are: (1) It was the right decision, (2) I regret the choice that was made; (3) I would go for the same choice if I had to do it over again; (4) The choice did me a lot of harm; (5) The decision was a wise one. Raw scores can be transformed to a 0–100 scale, where higher scores indicate greater decision regret. The DRS is quick to administer, normally requiring less than one minute, and can be used in both paper and digital formats. Psychometric evaluations have demonstrated high internal consistency. DRS scores correlate with measures of decision conflict, satisfaction with clinician communication, and physical and psychological outcomes. The DRS also discriminates between those who have changed their original decision and those who have not, and between individuals with positive versus negative emotional responses to their decision (37).

Phase one: Cultural and linguistic validation

The translation of the DRS into Maltese followed a structured and rigorous process to ensure both linguistic accuracy and conceptual validity. The methodology was guided by the collaborative and iterative translation framework proposed by Douglas and Craig (38), which emphasizes the active involvement of multidisciplinary teams throughout the translation process. This approach diverges from traditional forward–backward translation methods by prioritizing conceptual equivalence, cultural appropriateness, and semantic clarity over literal, word-for-word correspondence. As illustrated in Figure 2, the Douglas and Craig framework begins by identifying the source questionnaire, classifying question types based on the items of the DRS, and establishing category, functional, and conceptual equivalence. Translation is approached in parallel or double forms, with collaborative team review guiding decisions at each step. This leads to pretesting, followed by revisions and final administration. The cyclic nature of the model allows for iterative refinements based on consensus and evidence. This model was selected because it provides a transparent and replicable structure, making it especially suitable for health-related instruments like the DRS, where subtle semantic nuances could significantly impact item interpretation across languages and cultures.

Phase two: Quantitative and qualitative content validity

To further assess the content validity of the Maltese version of the DRS, both quantitative and qualitative approaches were employed, in accordance with the methodological standards outlined by the COSMIN initiative (29). A panel of eight subject matter experts was recruited to evaluate the relevance and clarity of each item in the translated version of the scale. Inclusion criteria for panellists included: (i) fluency in both English and Maltese; (ii) at least five years of professional experience in healthcare, health education, or psychometrics; and (iii) prior experience with scale development, validation, or patient-centred outcome measures. Experts who did not meet these criteria or who reported conflicts of interest with the study topic were excluded. Quantitative content validity was

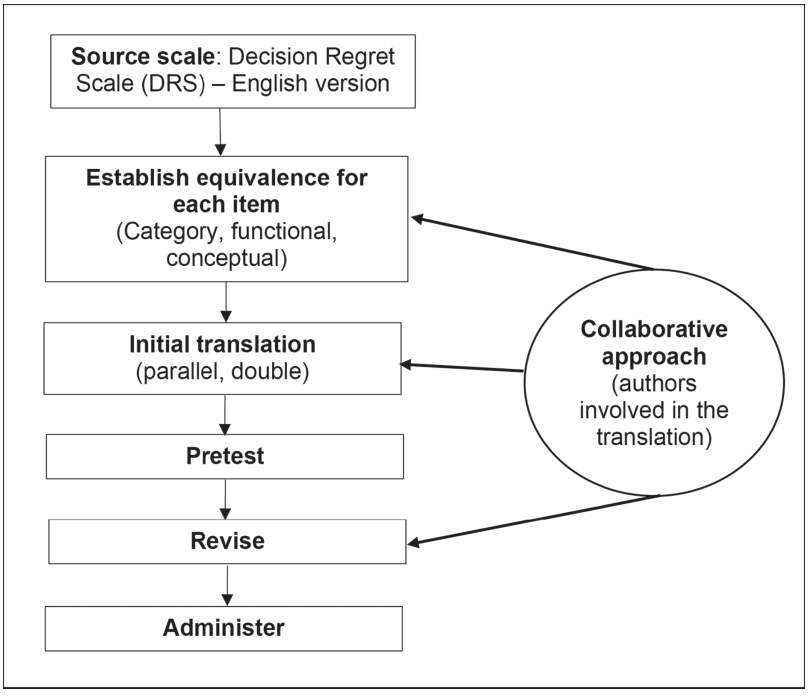

Figure 2. Adapted framework for the collaborative and iterative translation of the Decision Regret Scale (DRS) into Maltese, based on Douglas and Craig (2007).

assessed using the CVR and the CVI. For the CVR, each expert rated the relevance of each item on a 3-point Likert scale, where 1 indicated "not essential," 2 indicated "useful but not essential," and 3 indicated "essential." The CVR for each item was calculated using the formula:

$$CVR = \frac{n_e - (N/2)}{N/2} \quad (1)$$

Where n_e is the number of experts rating the item as essential, and N is the total number of experts. A CVR ≥ 0.75 was considered acceptable for a panel of eight experts (39). For the CVI, a 4-point Likert scale was used, where 1 indicated "not important," 2 indicated "somewhat important," 3 indicated "important," and 4 indicated "very important." The Item-level CVI (I-CVI) was calculated as the proportion of experts rating each item as either 3 or 4, divided by the total number of experts. The Scale-level CVI (S-CVI) was computed as the average of the I-CVIs across all items (39). Consistent with current recommendations (40), items with I-CVI values above 0.78 and an S-CVI greater than 0.80 were considered to have adequate content validity. Items that did not meet the established thresholds for CVR or CVI were discussed further and revised in a subsequent synthesis meeting involving the translation team and expert reviewers. Qualitative content validity (face validity) was assessed by inviting the same panel of experts to provide open-ended feedback on each item's clarity, cultural appropriateness, and conceptual alignment. Experts were encouraged to identify any wording they found ambiguous or problematic, suggest improvements, and comment on the overall coherence of the scale (39,40). This feedback was used to explore the face validity of the translated items, which is defined as the extent to which the items appear to measure the construct of decision regret on the surface.

Ethical considerations

Institutional review board approval was obtained from the University of Malta and the University of Rome Tor Vergata, which reviewed and approved the study protocol, including procedures for expert recruitment and informed participation (approval on 6th December 2024, protocol n. 6/CDS/2024). The project was also a specific supervised educational activity under the framework of the bilateral agreement governing international mobility activities (Erasmus+ Traineeship). No personal, health-related, or special category data were collected, and anonymity and confidentiality were ensured throughout the validation process. All participants were informed of the study's purpose, provided written consent, and were allowed to withdraw at any stage without consequences.

Results

Phase one: cultural and linguistic validation

A synthesis meeting was held, lasting approximately 90 minutes, during which the participants applied the collaborative and iterative translation framework (38). The review process was grounded in the collaborative and iterative framework proposed by Douglas and Craig, and focused on comparing the two independently produced forward translations, evaluating semantic nuances, and integrating feedback from the translation team. Particular attention was paid to achieving conceptual equivalence and cultural appropriateness. Each translated item was evaluated to determine the degree of agreement among the translation team. Particular attention was given to linguistic nuances, semantic clarity, and contextual relevance in the Maltese healthcare setting. A back-translation was independently performed by a native Maltese speaker fluent in English, and no substantial discrepancies were identified when compared to the original English version. This confirmed the fidelity of the translation, and the original scale developer formally endorsed the Maltese version. Preliminary pilot testing was conducted to further assess item clarity. Respondents consistently described the translated items as easily understandable and conceptually accessible. Notably, participants highlighted the "simplicity" and intuitive phrasing of the items, supporting the cultural relevance and linguistic adequacy of the final version.

Translation process

The translation of the DRS into Maltese involved a structured, multi-step process designed to ensure both linguistic accuracy and cultural appropriateness. The approach adhered to the collaborative and iterative methodology proposed by Douglas and Craig (38), emphasising conceptual rather than literal equivalence. The process began with two independent bilingual translators, both native speakers of Maltese, each producing a separate forward translation of the original English version of the DRS. This dual translation strategy ensured a diversity of linguistic interpretations and minimised individual bias. Following the initial translations, a synthesis meeting was convened, involving both translators and a bilingual reviewer. During this meeting, the team systematically compared the two translated versions, resolved discrepancies, and developed a unified Maltese version that best reflected the intended meaning of the original scale items. Subsequently, an expert review and adjudication phase was conducted by a panel composed of specialists in translation, psychometrics, and healthcare decision-making. Each item was examined in detail with particular attention to semantic clarity, conceptual alignment, and cultural appropriateness. Minor adjustments were made to enhance the clarity and relevance of the items within the Maltese healthcare context. The finalised translations of the five items were as follows. The original item "It was the right decision" was translated as "Kienet id-deċiżjoni t-tajba", and was unanimously accepted by the committee as linguistically accurate and culturally appropriate. The item "I regret the choice that was made" was rendered as "Jiddispjaċini mill-għażla li għamilt", a translation that retained the emotional tone of the original. The statement "I would go for the same choice if I had to do it over again" was translated as "Kieku kelli niddeċiedi mill-ġdid, kont nagħmel l-istess għażla", which the reviewers agreed conveyed the intended hypothetical reflection on choice repetition. The negatively phrased item "The choice did me a lot of harm" was translated into "L-għażla għamlitli ħafna ħsara", clearly capturing the connotation of negative consequences. Finally, "The decision was a wise one" was translated as "Id-deċiżjoni kienet waħda għaqlija", preserving the original's emphasis on sound judgment. Each translation was deemed faithful to the original items in both tone and meaning and suitable for use among Maltese-speaking patients in healthcare settings.

Phase two: quantitative and qualitative content validity

A panel of eight subject matter experts evaluated the relevance and clarity of each item in the translated Maltese version of the DRS. Panel characteristics are summarised in Table 1.

The first round of quantitative content validation, based on the calculation of the CVR and CVI, showed that most items were considered both relevant and appropriate. Specifically, all items exceeded the threshold criteria for content validity (CVR ≥ 0.75, I-CVI ≥ 0.78, and S-CVI ≥ 0.80), except for items 3 and 5, which fell slightly below the expected standards. To complement the quantitative analysis, a narrative analysis was conducted on the qualitative feedback provided by the expert panel. This feedback focused on the clarity, relevance, and conceptual distinctiveness of each item. Regarding item 3, several panellists noted that it appeared semantically similar to item 1. One expert remarked, "Quite similar to 1 above; possibly the translation did not capture the statement in the original scale," while another observed that the use of "niddeĊiedi" (I decide) and "għażla" (choice) in the same item might confuse respondents due to potential redundancy or ambiguity. For item 5, some panellists questioned whether the term "għaqlija" (wise) was meaningfully distinguishable from "t-tajba" (right), as used in item 1. One comment read, "How do you define 'għaqlija' (wise)? Does this mean the same thing to different people?" Another noted, "A wise decision is not necessarily different from 1 above." Based on these cċċonsiderations, a follow-up synthesis meeting was convened with the two original translators and the bilingual reviewer. During the 60-minute session, the team reviewed both the quantitative results and qualitative feedback. It was agreed that item 3 should be revised in light of its conceptual overlap and linguistic ambiguity. In contrast, the team opted to retain item 5 without modification, as they concluded that the distinction between a "right" and a "wise" decision remained theoretically sound and contextually appropriate. Additionally, the wording of the introductory statement of

Table 1. Characteristics of the panel of experts (n=8) in Phase 2 (quantitative and qualitative content validity)

		N (n = 8)	%
Gender			
	Males	1	12.5%
	Females	7	87.5%
Highest level of education			
	Postgraduate degree	2	25.0%
	Doctorate	6	75.0%
Occupation			
	Faculty (Academic)	3	37.5%
	Clinical Nurse	4	50.0%
	Registered audiologist and speech-language pathologist	1	12.5%
Work experience			
	5 -10 years	1	12.5%
	> 10 years	3	37.5%
	> 20 years	4	50.0%
Years (mean±DS)			49±10.5

the scale was revised to enhance conceptual clarity: the term "inti" (you) was added in bold to emphasise that the decision in question refers specifically to the patient's own choice, not one made by the clinician. Following these revisions, a second round of content validation was conducted. The revised scale, along with explanatory notes detailing the modifications, was redistributed to the same panel of experts. All five items were then rated as relevant and appropriate, with CVR values equal to 1, as well as I-CVIs (all = 1), and S-CVI (=1). These results confirmed that the revised version met the established thresholds for content validity, and the scale was consequently approved for use in the Maltese context (see Table 2).

Discussion

The primary aim of this study was to develop and evaluate the content validity of the Maltese version of the DRS. A multi-phase methodological approach was employed to ensure that the translated instrument maintained the conceptual integrity of the original while achieving linguistic and cultural appropriateness for use in the Maltese healthcare context (38). The collaborative translation process, which followed the iterative model proposed by Douglas and Craig (38), enabled the research team to go beyond literal equivalence and ensure that the translated items reflected the emotional and cognitive dimensions of decision regret as experienced by patients. The consensus meeting between independent translators and bilingual experts played a central role in resolving discrepancies and ensuring fidelity to the source scale. Moreover, pilot testing confirmed that the translated items were clear and easily understood, reinforcing the appropriateness of the chosen wording in the target population (41). The results of the content validity analyses further supported the adequacy of the Maltese version. In the initial round, three of the five items met or exceeded the recommended thresholds for CVR, I-CVI, and S-CVI, while two items (Items 3 and 5) were flagged for potential issues related to semantic overlap and conceptual clarity. These concerns were appropriately addressed in a second expert consensus session, during which Item 3 was revised to resolve linguistic ambiguity, and Item 5 was retained after reasoned discussion of its conceptual distinctiveness. The decision to emphasise the respondent's perspective by inserting "inti" (you) in the introductory instructions also reflects a thoughtful adaptation to the patient-centred cultural framing in the Maltese context, even though the personal pronoun is often dropped in written and especially spoken Maltese. Notably, similar challenges were encountered during the Italian translation and validation of the DRS, particularly with item 3, which involves a conditional construct that can be semantically ambiguous, and item 5, which requires a nuanced distinction between "right" and "wise" decisions (42). The second round of validation confirmed that all five items met the established thresholds for content validity, demonstrating high expert agreement on both relevance and clarity. These findings provide robust preliminary evidence in support of the content and face validity of the Maltese DRS. The use of a mixed-methods approach, quantitative indices supported by qualitative expert feedback, strengthens the methodological

Table 2. Maltese Version of the Decision Regret Scale (Skala ta' Dispja·ir dwar De·iżjoni)

Maltese version **Skala ta' Dispjaċir dwar Deċiżjoni** Jekk jogħġbok, aħseb dwar id-deċiżjoni li inti ħadt dwar _____ wara li tkellimt ma' [tabib/a, kirurgu, infermier/a, professjonist/a fil-qasam tas-saħħa, eċċ.]. Uri kemm taqbel ma' dawn l-istqarrijiet billi tagħżel numru minn 1 (naqbel ħafna) sa 5 (ma naqbilx ħafna).					
1. 1.Kienet id-deċiżjoni t-tajba	1 Naqbel ħafna	2 Naqbel	3 La naqbel u lanqas ma naqbilx	4 Ma naqbilx	5 Assolutament ma naqbilx
2. Jiddispjaċini mill-għażla li għamilt	1 Naqbel ħafna	2 Naqbel	3 La naqbel u lanqas ma naqbilx	4 Ma naqbilx	5 Assolutament ma naqbilx
3. Kieku kelli nagħżel mill-ġdid, kont nagħmel l-istess għażla	1 Naqbel ħafna	2 Naqbel	3 La naqbel u lanqas ma naqbilx	4 Ma naqbilx	5 Assolutament ma naqbilx
4. L-għażla għamlitli ħafna ħsara	1 Naqbel ħafna	2 Naqbel	3 La naqbel u lanqas ma naqbilx	4 Ma naqbilx	5 Assolutament ma naqbilx
5. Id-deċiżjoni kienet waħda għaqlija	1 Naqbel ħafna	2 Naqbel	3 La naqbel u lanqas ma naqbilx	4 Ma naqbilx	5 Assolutament ma naqbilx
English version **Decision Regret Scale** Please think about the decision you made about _____ after talking to your [doctor, surgeon, nurse, health professional, etc.]. Please show how you feel about these statements by circling a number from 1 (strongly agree) to 5 (strongly disagree).					
1. 1It was the right decision	1 – Strongly Agree	2 – Agree	3 – Neither Agree Nor Disagree	4 – Disagree	5 – Strongly Disagree
2. I regret the choice that was made	1 – Strongly Agree	2 – Agree	3 – Neither Agree Nor Disagree	4 – Disagree	5 – Strongly Disagree
3. I would go for the same choice if I had to do it over again	1 – Strongly Agree	2 – Agree	3 – Neither Agree Nor Disagree	4 – Disagree	5 – Strongly Disagree
4. The choice did me a lot of harm	1 – Strongly Agree	2 – Agree	3 – Neither Agree Nor Disagree	4 – Disagree	5 – Strongly Disagree
5. The decision was a wise one	1 – Strongly Agree	2 – Agree	3 – Neither Agree Nor Disagree	4 – Disagree	5 – Strongly Disagree

Note: Table 2a presents the Maltese version of the Decision Regret Scale. Table 2b shows the original English version, as developed by O'Connor (1996).

rigour and aligns with COSMIN guidelines for the cross-cultural adaptation of patient-reported outcome measures (30,43). This study represents an essential first step in making a validated tool available for assessing DR among Maltese-speaking patients, particularly those managing NCDs. Given the increasing burden of NCDs in Malta and the centrality of shared decision-making in long-term care, the availability of a culturally adapted regret measure offers significant value for both clinical practice and patient-centred research (44–46). It opens the door to better understanding how patients reflect on past treatment choices and to developing targeted interventions that may mitigate regret and improve adherence, satisfaction, and long-term outcomes. Nonetheless, while this study confirms the content validity of the translated DRS, further research is required to establish its construct validity, reliability, and responsiveness in clinical settings. Future studies should explore the scale's psychometric performance using factor analysis and test-retest reliability, and assess its associations with related constructs such as decision conflict, quality of life, and patient engagement. In addition, studies involving specific patient populations across various NCD contexts (e.g., oncology, cardiology, diabetes) would help establish its broader applicability. This study has several limitations that should be acknowledged. First, the validation process was limited to content and face validity, as defined by COSMIN guidelines. It did not include assessments of construct validity, criterion validity, internal consistency, or test-retest reliability (47,48). These are essential components of a comprehensive psychometric evaluation and are required to fully establish the measurement properties of the Maltese version of the DRS. Second, although expert consensus was robust and the panel included professionals with diverse backgrounds, the absence of direct input from patients during the validation phase may limit the generalizability of the findings to real-world clinical settings. Furthermore, the sample size of eight experts, while acceptable for content validation procedures, may restrict the variability of perspectives, particularly in a multicultural population such as Malta's (49). Future research should focus on completing the remaining psychometric steps outlined by COSMIN (50). Specifically, studies involving larger and heterogeneous patient populations are needed to assess the construct validity of the scale through exploratory and confirmatory factor analyses. In addition, evaluations of internal consistency (e.g., Cronbach's alpha), test-retest reliability (e.g., intraclass correlation coefficients), and measurement error should be conducted. Responsiveness to change and cross-cultural measurement invariance should also be explored in clinical populations with non-communicable diseases, where decision regret plays a critical role in long-term engagement and outcomes (51). These future studies will be essential to ensure that the Maltese version of the DRS is psychometrically sound and suitable for both clinical practice and research applications.

Conclusions

The research study reported in this paper translated and content-validated the Maltese version of the DRS, following a rigorous translation methodology and expert-driven evaluation process. The findings provide strong preliminary evidence supporting the cultural, linguistic, and content validity of the adapted instrument. This study represents an important first step toward the full psychometric validation of the DRS in the Maltese context. Given the increasing emphasis on patient-centred care and shared decision-making, especially among individuals living with non-communicable diseases, the availability of a culturally adapted tool for measuring decision regret is both timely and relevant. The Maltese DRS represents a foundational step toward enabling clinicians and researchers to better understand and explore patient experiences of decision regret in the local context. Once fully validated, it may inform future efforts to improve treatment engagement, patient satisfaction, and long-term health outcomes through more person-centred decision-making processes. Further studies are warranted to complete the psychometric evaluation of the scale, including assessments of construct validity, reliability, responsiveness, and measurement invariance. These next steps are essential to ensure that the instrument is psychometrically robust and fit for use in both clinical and research settings.

Ethic Approval: Institutional review board approval was obtained from the University of Malta and the University of Rome Tor Vergata, which reviewed and approved the study protocol, including procedures for expert recruitment and informed participation (approval on 6th December 2024).

Conflict of Interest: Each author declares that he or she has no commercial association (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangements etc.) that might pose a conflict of interest with the submitted article.

Authors Contribution: A.S.B. conceived the study, led the methodological design, and coordinated the validation process. J.L.M., J.T., and M.C. contributed to the cultural adaptation and data collection phases in the Maltese context. G.C., A.M., and S.B. supported data analysis and interpretation. P.M.P. and S.C. contributed to the critical revision of the manuscript and provided methodological oversight. C.A. and R.C. supervised the study, ensured alignment with COSMIN standards, and contributed to manuscript drafting and final approval. All authors reviewed and approved the final version of the manuscript.

Declaration on the Use of AI: Grammarly, an AI-based writing assistant, was used solely to improve the readability and grammar of the manuscript. After utilising this tool, the authors carefully reviewed and edited the content as needed and take full responsibility for the final version of the publication. All scientific content was conceived and written by the authors.

Consent for Publication: Not applicable. This study did not involve the collection of identifiable personal data from human participants.

Acknowledgements: The authors would like to express their sincere gratitude to all the faculty members of the University of Malta whom the first author had the pleasure of meeting during an Erasmus mobility experience as part of a PhD program. Their insights, support, and collegiality greatly enriched the development of this study. In addition, the authors acknowledge support from the University of Milan through the APC initiative.

Funding: None.

References

1. Nugent R. Preventing and managing chronic diseases. BMJ. 2019 Jan 31;364:l459. doi: 10.1136/bmj.l459.
2. Verweel L, Newman A, Michaelchuk W, Packham T, Goldstein R, Brooks D. The effect of digital interventions on related health literacy and skills for individuals living with chronic diseases: A systematic review and meta-analysis. Int J Med Inform. 2023 Sep;177:105114. doi: 10.1016/j.ijmedinf.2023.105114.
3. Wang Y, Wang J. Modelling and prediction of global non-communicable diseases. BMC Public Health. 2020 Jun 1;20(1):822. doi: 10.1186/s12889-020-08890-4.
4. NCD Countdown 2030 collaborators. NCD Countdown 2030: worldwide trends in non-communicable disease mortality and progress towards Sustainable Development Goal target 3.4. Lancet. 2018 Sep 22;392(10152):1072-88. doi: 10.1016/S0140-6736(18)31992-5.
5. Rajashekhar M, Joshi M, Mundra A, et al. Community-based health promotion interventions to reduce risk factors of non-communicable diseases among adolescent and young adults in low- and middle-income countries: A systematic review and meta-analysis. Public Health. 2025 Jun;243:105714. doi: 10.1016/j.puhe.2025.03.026.
6. Dumcheva A, Nevalainen J, Laatikainen T, Nuorti P. How likely are Eastern European and central Asian countries to achieve global NCD targets: multi-country analysis. BMC Public Health. 2024 Oct 5;24(1):2714. doi: 10.1186/s12889-024-20186-5.
7. GBD 2021 Causes of Death Collaborators. Global burden of 288 causes of death and life expectancy decomposition in 204 countries and territories and 811 subnational locations, 1990-2021: a systematic analysis for the Global Burden of Disease Study 2021. Lancet (London, England). 2024 May 18;403(10440): 2100–32. doi: 10.1016/S0140-6736(24)00367-2.
8. NCD Countdown 2030 collaborators. NCD Countdown 2030: efficient pathways and strategic investments to accelerate progress towards the Sustainable Development Goal target 3.4 in low-income and middle-income countries. Lancet. 2022 Mar 26;399(10331):1266-78. doi: 10.1016/S0140-6736(21)02347-3.
9. Hacker K. The Burden of Chronic Disease. Mayo Clin Proc Innov Qual Outcomes. 2024 Jan 20;8(1):112-119. doi: 10.1016/j.mayocpiqo.2023.08.005. Erratum in: Mayo Clin Proc Innov Qual Outcomes. 2024 Dec 13;9(1):100588. doi: 10.1016/j.mayocpiqo.2024.11.005.
10. Schneiderman N. Psychosocial, Behavioral, and Biological Aspects of Chronic Diseases. Current Directions in Psychological Science. Sage Journals 2004 Dec;13(6): 247–51. doi:10.1111/j.0963-7214.2004.00318.x.
11. Budreviciute A, Damiati S, Sabir DK, et al. Management and Prevention Strategies for Non-communicable Diseases (NCDs) and Their Risk Factors. Front Public Health. 2020 Nov 26;8:574111. doi: 10.3389/fpubh.2020.574111.
12. OECD. State of Health in the EU: Country Health Profiles. OECD; 2023. doi:10.1787/25227041. https://www.oecd.org/en/publications/state-of-health-in-the-eu_25227041.html [Accessed 17th May 2025].

13. Ministry For Health and Active Ageing. A National Health Systems Strategy for Malta 2023 - 2033. 2024 [Accessed 17th May 2025]. p. 1–83. https://health.gov.mt/wp-content/uploads/2024/09/A_National_Health_Systems_Strategy_for_Malta_2023_2033_September_2024.pdf [Accessed 17th May 2025].
14. Agius R, Pace NP, Fava S. Characterisation of body size phenotypes in a middle-aged Maltese population. J Nutr Sci. 2021 Sep 24;10:e81. doi: 10.1017/jns.2021.74.
15. Mifsud JL, Galea J. Cardiovascular Risk Factors Among First-Degree Relatives of Patients with Premature Cardiovascular Disease in Malta. Baseline Findings from the CRISO Project. Vasc Health Risk Manag. 2024 Apr 9;20:167-76. doi: 10.2147/VHRM.S449672.
16. Mainz J, Kristensen S, Roe D. The power of the patient's voice in the modern health care system. Int J Qual Health Care. 2022 Mar 30;34(34 Suppl 1):ii1-ii2. doi: 10.1093/intqhc/mzac001.
17. Dang-Vu G, Rein L, Szabo A, Venkatesan T. Low patient engagement is associated with reduced health-related quality of life in adults with cyclic vomiting syndrome. Scand J Gastroenterol. 2022 Sep;57(9):1030-35. doi: 10.1080/00365521.2022.2064724.
18. Veenendaal HV, Chernova G, Bouman CM, Etten-Jamaludin FSV, Dieren SV, Ubbink DT. Shared decision-making and the duration of medical consultations: A systematic review and meta-analysis. Patient Educ Couns. 2023 Feb;107:107561. doi: 10.1016/j.pec.2022.11.003.
19. Selby LV, Aquina CT, Pawlik TM. When a Patient Regrets Having Undergone a Carefully and Jointly Considered Treatment Plan, How Should Her Physician Respond? AMA J Ethics. 2020 May 1;22(5):E352-57. doi: 10.1001/amajethics.2020.352.
20. Korkidakis A, Martinez S, Sabbagh R, et al. Decision-making in women who considered planned oocyte cryopreservation: decision satisfaction or regret? Reprod Biomed Online. 2025 Feb;50(2):103944. doi: 10.1016/j.rbmo.2024.103944.
21. Liu J, Hunter S, Zhu J, Lee RL, Chan SW. Decision regret regarding treatments among women with early-stage breast cancer: a systematic review protocol. BMJ Open. 2022 Mar 17;12(3):e058425. doi: 10.1136/bmjopen-2021-058425.
22. Pearson H H, Bryan G, Kayum C, Gibson F, Darlington AS. Parent values and preferences underpinning treatment decision-making in poor-prognosis childhood cancer: a scoping review. BMC Pediatr. 2022 Oct 14;22(1):595. doi: 10.1186/s12887-022-03635-1.
23. Brera AS, Arrigoni C, Magon A, et al. Mapping the literature on decision regret in patients with non-communicable diseases (NCDs): a scoping review protocol. BMJ Open. 2023 Jul 18;13(7):e072703. doi: 10.1136/bmjopen-2023-072703.
24. Brera AS, Arrigoni C, Magon A, et al. A scoping review of decision regret in non-communicable diseases: The emerging roles of patient-clinician communication, psychological aspects, and medical outcomes. Patient Educ Couns. 2025 Jan;130:108478. doi: 10.1016/j.pec.2024.108478.
25. Wu CJ, Yeh TP, Chu G, Ho YF. Effectiveness of computerised decision aids for patients with chronic diseases in shared decision-making: A systematic review and meta-analysis. J Clin Nurs. 2024 Jul;33(7):2732-54. doi: 10.1111/jocn.17095.
26. Tews AM, Hinz A, Magnus V, et al. Decision regret in patients with head-and-neck cancer undergoing radiotherapy. Clin Transl Radiat Oncol. 2025 Jun 27;54:101005. doi: 10.1016/j.ctro.2025.101005.
27. Chehade M, Mccarthy MM, Squires A. Patient-related decisional regret: An evolutionary concept analysis. J Clin Nurs. 2024 Nov;33(11):4484-4503. doi: 10.1111/jocn.17217.
28. Brehaut JC, O'Connor AM, Wood TJ, et al. Validation of a decision regret scale. Med Decis Making. 2003 Jul-Aug; 23(4):281-92. doi: 10.1177/0272989X03256005.
29. Mokkink LB, Terwee CB, Patrick DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. Qual Life Res. 2010 May;19(4):539-49. doi: 10.1007/s11136-010-9606-8.
30. Caruso R, Arrigoni C, Groppelli K, et al. Italian version of Dyspnoea-12: cultural-linguistic validation, quantitative and qualitative content validity study. Acta Biomed. 2018 Jan 16;88(4):426-34. doi: 10.23750/abm.v88i4.6341.
31. Clark JA, Wray N, Brody B, Ashton C, Giesler B, Watkins H. Dimensions of quality of life expressed by men treated for metastatic prostate cancer. Soc Sci Med. 1997 Oct;45(8):1299-309. doi: 10.1016/s0277-9536(97)00058-0.
32. Clark JA, Wray NP, Ashton CM. Living with treatment decisions: regrets and quality of life among men treated for metastatic prostate cancer. J Clin Oncol. 2001 Jan 1;19(1):72-80. doi: 10.1200/JCO.2001.19.1.72.
33. Zeelenberg M, Beattie J. Consequences of Regret Aversion 2: Additional Evidence for Effects of Feedback on Decision Making. Organizational Behavior and Human Decision Processes. 1997 Oct 20;72(1): 63–78. doi:10.1006/obhd.1997.2730.
34. Creyer EH, Ross WT. The Development and Use of a Regret Experience Measure to Examine the Effects of Outcome Feedback on Regret and Subsequent Choice. Marketing Letters. 1999;10(4): 379–92. doi: 10.1023/A:1008166305455
35. Tsiros M, Mittal V. Regret: A Model of Its Antecedents and Consequences in Consumer Decision Making. Journal of Consumer Research. 2000 Feb;26(4): 401–17. doi: 10.1086/209571.
36. Inman JJ, Zeelenberg M. Regret in Repeat Purchase versus Switching Decisions: The Attenuating Role of Decision Justifiability. Journal of Consumer Research. 2002 Feb;29(1): 116–28. doi:10.1086/339925.
37. Horst SJ. Critical Synthesis Package: Decision Regret Scale. MedEdPORTAL. 2015 Jul 21;11:10147. doi:10.15766/mep_2374-8265.10147
38. Douglas SP, Craig CS. Collaborative and Iterative Translation: An Alternative Approach to Back Translation. Journal

of International Marketing. 2007;15(1): 30–43. https://doi.org/10.1509/jimk.15.1.030.
39. Spoto A, Nucci M, Prunetti E, Vicovaro M. Improving content validity evaluation of assessment instruments through formal content validity analysis. Psychol Methods. 2025 Apr;30(2):203-22. doi: 10.1037/met0000545.
40. Almanasreh E, Moles RJ, Chen TF. A practical approach to the assessment and quantification of content validity. In: Desselle SP, García-Cárdenas V, Anderson C, Aslani P, Chen AMH, Chen TF, editors. Contemporary Research Methods in Pharmacy and Health Services. London: Academic Press; 2022. p. 583–599. doi:10.1016/B978-0-323-91888-6.00013-2.
41. Ivziku D, Caruso R, Lommi M, et al. Cultural Adaptation and Psychometric Properties of the Trust Me Scale-Italian Version: A Validation Study. Healthcare (Basel). 2023 Apr 11;11(8):1086. doi: 10.3390/healthcare11081086.
42. Brera AS, Arrigoni C, Belloni S, et al. Decision Regret and Vaccine Hesitancy among Nursing Students and Registered Nurses in Italy: Insights from Structural Equation Modeling. Vaccines (Basel). 2024 Sep 14;12(9):1054. doi: 10.3390/vaccines12091054.
43. Content Validity Ratio. In: The SAGE Encyclopedia of Educational Research, Measurement, and Evaluation. 2455 Teller Road, Thousand Oaks, California 91320: SAGE Publications, Inc.; 2018. doi:10.4135/9781506326139.n151. [Accessed 17th May 2025].
44. Cuschieri S, Pallari E, Hatziyianni A, Sigurvinsdottir R, Sigfusdottir ID, Sigurðardóttir ÁK. Mortality comparisons of COVID-19 with all-cause and non-communicable diseases in Cyprus, Iceland and Malta: lessons learned and forward planning. Public Health. 2022 Jan;202:52-7. doi: 10.1016/j.puhe.2021.03.025.
45. GBD 2021 Diseases and Injuries Collaborators. Global incidence, prevalence, years lived with disability (YLDs), disability-adjusted life-years (DALYs), and healthy life expectancy (HALE) for 371 diseases and injuries in 204 countries and territories and 811 subnational locations, 1990-2021: a systematic analysis for the Global Burden of Disease Study 2021. Lancet. 2024 May 18;403(10440):2133-61. doi: 10.1016/S0140-6736(24)00757-8.
46. GBD 2019 Diseases and Injuries Collaborators. Global burden of 369 diseases and injuries in 204 countries and territories, 1990-2019: a systematic analysis for the Global Burden of Disease Study 2019. Lancet. 2020 Oct 17;396(10258):1204-22. doi: 10.1016/S0140-6736(20)30925-9. Erratum in: Lancet. 2020 Nov 14;396(10262):1562. doi: 10.1016/S0140-6736(20)32226-1.
47. Terwee CB, Prinsen CAC, Chiarotto A, et al. COSMIN methodology for evaluating the content validity of patient-reported outcome measures: a Delphi study. Qual Life Res. 2018 May;27(5):1159-70. doi: 10.1007/s11136-018-1829-0.
48. Baroni I, Paglione G, De Angeli G, et al. A COSMIN systematic review of instruments for evaluating health-related quality of life in people with Hereditary Angioedema. Health Qual Life Outcomes. 2025 Feb 13;23(1):12. doi: 10.1186/s12955-025-02342-6.
49. Roebianto A, Savitri I, Aulia Syaiful I, Suciyana Sriyanto A, Mubarokah L. Content validity: Definition and procedure of content validation in psychological research. Testing, Psychometrics, Methodology in Applied Psychology. 2023 March;30(1): 5–18. doi:10.4473/TPM30.1.1.
50. Mokkink LB, Terwee CB, Patrick DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. J Clin Epidemiol. 2010 Jul;63(7):737-45. doi: 10.1016/j.jclinepi.2010.02.006.
51. Chiarotto A, Ostelo RW, Boers M, Terwee CB. A systematic review highlights the need to investigate the content validity of patient-reported outcome measures for physical functioning in patients with low back pain. J Clin Epidemiol. 2018 Mar;95:73-93. doi: 10.1016/j.jclinepi.2017.11.005.

Correspondence:
Received: 27 May 2025
Accepted: 29 July 2025
Rosario Caruso, PhD, RN, FESNO, FAAN
Department of Biomedical Sciences for Health,
University of Milan, Milan, Italy
Via Pascal 36, 20133, Milan, Italy.
E-mail: rosario.caruso@unimi.it
ORCID: 0000-0002-7736-6209