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1 **Evaluating self-reported pressure ulcer prevention measures in persons with**
2 **spinal cord injury using the revised Skin Management Needs Assessment**
3 **Checklist : reliability study**

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1 Abstract:

2 Objective: to translate, evaluate the reliability and cross-culturally adapt the Skin
3 Management Needs Assessment Checklist, a questionnaire evaluating the knowledge
4 on pressure ulcer prevention measures in persons with spinal cord injury.

5 Study design: Cross-cultural adaptation and reliability study.

6 Subjects: 138 persons with spinal cord injury, mean age 45.9 years, mean time since
7 injury 94 months.

8 Material and method: The study was carried out in 2 stages. First, the questionnaire
9 went through a forward-backward translation process and was cross-culturally
10 adapted, according to a validated methodology for self-reported measures. Then, the
11 test-retest reliability was evaluated on a population of persons with spinal cord injury

12 Results: The standardized back-translation and cross-cultural adaptation led to the
13 revised Smack grid, with the addition of 7 items representing an update of pressure
14 ulcer prevention measures. The reliability was excellent (intraclass correlation
15 coefficient: 0.899).

16 Conclusion: The revised SMnac is an adaptation of the SMnac, including therapeutic
17 education frameworks and the latest pressure ulcer prevention practices. It appears to
18 be a reliable tool for assessing the knowledge and benefits of pressure ulcer
19 prevention in persons with spinal cord injury. Further studies are needed to explore
20 its validity and responsiveness to change.

21 Keywords: knowledge, education, prevention, spinal cord injury, weight pressure
22 relief, behaviors

23

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7 **Introduction**

8 Pressure ulcer is a common complication in persons with spinal cord injury
9 (SCI). It affects around 20 % of patients living at home (1); and thus is a major
10 challenge for the Public Health Care System both on a medical level (high rate of
11 associated complications) as well as economical level (extended duration of hospital
12 stays, multiple hospital stays)..

13 Multiple risk factors were identified in persons with chronic spinal cord
14 injury : social and demographical, neurological but also behavioral factors (2-3).

15 Several of these factors cannot benefit from a targeted prevention. However,
16 Physical Medicine and Rehabilitation (PM&R) professionals can and must have an
17 impact on some of these factors, right from the initial acute phase, such as behavioral
18 factors, by educating patients on skin lesion prevention (4-5).

19 One of the objectives of an initial PM&R hospital stay is to enable the patient
20 to take charge of his/her own health by implementing proper measures for preventing
21 potential skin damages at home.

22 As soon as an educational strategy is defined for persons with SCI, it is
23 essential to have the necessary means to evaluate the impact of this strategy not only
24 on patients' knowledge but also on self-implemented prevention measures. Most
25 studies in the literature were conducted for evaluating the impact of a standardized

1 therapeutic education on pressure ulcer (PU) recurrence, patients' knowledge in
2 terms of preventive measures only came as a secondary assessment(6-7). The
3 questionnaires used to evaluate patient's knowledge were designed within the
4 framework of these studies and their metrological qualities are unknown.

5 The SMnac, a self-administered questionnaire, is highly relevant because it
6 was designed and focused on assessing patient's knowledge and self-reported
7 prevention measures in terms of skin lesions (8). It includes 12 questions divided into
8 3 different categories: « Skin checks », « preventing pressure ulcers », « preventing
9 wounds ».

10 It corresponds to the Skin chapter of the NAC (Needs Assessment Checklist)
11 (9), which is a self-administered questionnaire listing the PM&R objectives of
12 persons with spinal cord injury. This questionnaire was validated in the English
13 language.

14 The SMnac English language validation was conducted on 317 patients (8),
15 and reported good internal consistency (Cronbach : 0.85), as well as a good
16 responsiveness to change. The test-retest reproducibility for SMnac is 0.90(9-10).

17 The objectives of this study were first to translate, cross-culturally adapt in
18 light of the latest PU prevention practices and secondly conduct a reproducibility
19 study on the revised SMnac scale.

20 **Materials and Methods**

21 This study was carried out in 2 stages. First, the SMnac was submitted to a forward-
22 backward translation process and a cross-cultural adaptation. Then, the test-retest
23 reliability was assessed in persons with SCI. The study protocol was approved by the
24 Ethical Committee of Southern France (*Comité de Protection des Personnes Sud*
25 *Méditerranée 3 Nîmes, France*).

1 **Skin Management Needs Assessment Checklist (SMnac)**

2 SMnac is derived from the Needs Assessment Checklist (NAC) with 9 areas
3 to explore the PM&R indicators specific to persons with SCI. SMnac corresponds to
4 the Skin Management area and aims at evaluating the self-reported prevention
5 measures of persons with SCI as well as their knowledge regarding SCI-related skin
6 disorders.

7 This self-administered questionnaire includes 12 questions divided into three
8 categories: “skin checks” , “preventing pressure ulcer” and “preventing wounds”.

9 The 12th question relates to buying a mirror for skin checks but it is not computed
10 into the final score. Each item is scored from 0 to 3 (0=completely dependent, never
11 does to 3 = completely independent, always does or instructs someone to). The total
12 score is expressed as a percentage.

13 **Forward-backward translation**

14 The objective of this phase was to translate, as accurately as possible the English
15 version of the SMnac, into French. The translation methodology followed the good
16 practices translation guidelines for self-reported measures (11-12). The back-
17 translation technique is described below.

18 The translation was done by a professional translator, native French Speaker, with a
19 university degree in medical and scientific English translations (Bénédicte Clement).

20 It was recommended to do a literal-idiomatic translation – i.e. keeping the true
21 meaning and achieving the closest natural equivalent of each item – rather than
22 word-for-word translation. A meeting was scheduled with the Coordination
23 Committee in order to bring up problems encountered during the translation and
24 resolve any disparities.

1 The backward translation had to be conducted by a native English speaker and
2 professional translator (Teresa Sawyers). This step was essential to ensure that the
3 meaning of each item was correlated to the original English version. Another
4 meeting with the Coordination Committee was scheduled to bring up any unresolved
5 issues. .

6 The concordance assessment between the original SMnac version and the back-
7 translated version was conducted by the British team who designed the original scale,
8 headed by Paul Kennedy in the United Kingdom (6 experts).

9 The concordance was evaluated item per item according to the methodology
10 described by Sperber et al (13). Each expert rated each item according to two
11 parameters: (1) *Comparability of language*: do the words or sentences match and (2)
12 *Similarity of interpretation*: do the items have a similar meaning (even if the words
13 are different). For each item we calculated the mean of responses and came up with a
14 number. In order to validate the translation we needed to have a comparability of
15 language < 3 or a similarity of interpretation < 2.5 . In case of disparity, the forward
16 and backward translation process of the item needed to be done again until reaching
17 a definite agreement.

18 **Cross-cultural adaptation**

19 *Acceptability and feasibility study of the pre-final version of the SMnac*

20 The objective of this study was to evaluate the acceptability and feasibility of the
21 forward-backward translated SMnac scale before its cross-cultural adaptation (pre-
22 final version) on a population of persons with SCI. The patients were persons with
23 SCI regardless of its etiology. Exclusion criteria were: cognitive or psychiatric
24 disorders, unstable medical condition and also poor mastering of the French
25 language.

1 The recruitment was done by the PM&R and Neurological Center PROPARA
2 (*Centre Neurologique Mutualiste PROPARA* Montpellier, France). The evaluations
3 were conducted by the main author (AG). After giving the patient information on the
4 study's objectives, the examiner handed-out the SMnac's pre-final version. No
5 guidelines were given to the patient besides the requirement to answer all questions.
6 The questionnaire was collected back one to two hours later and patients were invited
7 to voice their comments and remarks during a semi-guided individual interview.
8 First, patients spoke up freely before the examiner went through the main questions
9 (objective of the scale, time spent completing the scale, the way items are described,
10 scoring description, overall comments on the scale).

11 ***Content validity***

12 Content validity refers to the extent to which a measure represents all facets of
13 the categories to be measured, and that each category is represented by an adequate
14 number of items according to its relevance.

15 The scale was reviewed by 3 nationally recognized experts on persons with
16 spinal cord injury and pressure ulcers (PAJ, TA and DC), their goal was to adapt the
17 scale to the latest prevention practices used in PM&R units.

18 This expertise was performed in two stages:

19 - First an individual meeting was set up with each expert. The meeting started with a
20 presentation of the theoretical framework and objectives of the scale. Then the expert
21 shared his/her remarks and comments on the revised scale: domains explored, critics
22 of the items selected and categories defined, highlighting missing items in some pre-
23 examined areas. Lastly, a summary of the meeting(s) with the previous expert(s) was
24 presented.

1 - After these meetings, the coordination committee made changes to the SMnac and
2 gave it back to the experts for final validation and approval (PAJ, TA and DC).

3 ***Acceptability study of the SMnac revised version***

4 The study's methodology was strictly similar to the first acceptability study.

5 **Reliability study**

6 The test-retest reproducibility was assessed on a sample of persons with SCI
7 who met the same inclusion criteria defined for the acceptability study. The
8 investigator gave the patients clear and precise information and collected their signed
9 consent form.

10 The persons included in the study answered the questionnaire twice with a 4-
11 day interval in between. During the first administration of the questionnaire, the
12 items were listed at random in order to decrease the risk of memory biases.

13 **Statistical analysis**

14 To evaluate the correlation degree between the various scores at D1 and D4,
15 the intraclass correlation coefficients (ICC) were calculated. The reproducibility was
16 classified, according to the Landis and Koch classification (14), as excellent
17 ($0.8 < ICC \leq 1$), good ($0.6 < ICC \leq 0.8$), fair ($0.4 < ICC \leq 0.6$), poor ($0.2 < ICC \leq 0.4$), or bad
18 ($0 < ICC \leq 0.2$).

19 To evaluate the correlation level of all questions between D1 and D4, the
20 Kappa coefficient agreement was calculated. The significance threshold is $p < \square 0.05$.
21 Weighted Kappa coefficient was calculated with a 95% confidence interval for
22 ordinal modalities. For data analysis we used the S.A.S. software version 9.1. and R.

23 **Results**

24 **Translation/back-translation** (table 1)

1 During the first translation/back-translation cycle, the comparability of
2 language analysis led to the validation of half the items. The similarity of
3 interpretation analysis did not validate any additional item. The discordant items
4 were submitted to a second translation and back-translation cycle using the same
5 modalities. All items were validated during the second cycle.

6 **Cross cultural adaptation**

7 *Acceptability study for the pre-final SMnac version*

8 19 patients were included in the study. Mean age 42 years (Range: 16-74, SD
9 = 18), 79% of them were men.

10 The qualitative analysis focused on the comments and remarks formulated by
11 patients and the evaluator's observations during the individual meetings.

12 - The SMnac objective was well understood by patients. For 16 patients, the
13 notion of PU prevention was mentioned. The other 3 patients extended this notion to
14 skin disorders in general. 6 patients noted the notion of evaluating knowledge and
15 self-reported prevention measures, and 2 patients reported the notion of autonomy in
16 PU prevention.

17 - The questionnaire was reported as time-consuming by only one patient. This
18 elderly patient, affected by a recent metastatic epidural spinal cord compression with
19 associated paraplegia believed that pressure ulcer prevention was the sole
20 responsibility of healthcare professionals.

21 - Regarding items' description, 12 patients did not report any
22 miscomprehension issues. The remarks made by patients were mainly on two items,
23 that each included two distinct questions with only one possible answer.

24 Furthermore, 3 patients suggested including additional at-risk situations, according to
25 their personal experience (sports practice, car driving and heaters for burns risks). A

1 patient noted the lack of question on the choice or maintenance of specific PU
2 prevention equipments (e.g. mattress, wheelchair cushions).

3 - The scoring modalities raised more difficulties for patients since only 5 of them
4 found them to be precise and clear. Their remarks were divided into four categories:
5 the answers were not directly related to the question, but located at the top of the
6 document thus the patient needed to go back and forth several times (N=8), the fact
7 of having three possible answers for each scoring level was deemed as complex
8 (N=6), no patient used the answer N/A, finally for some questions, the answer grid
9 was inadequate since the question could only lead to a Yes/No answer (N=4).

10 - Most patients had a positive opinion of the questionnaire.

11 Only three patients had a negative opinion of the questionnaire that could be
12 explained by their very recent spinal cord injury (less than one month).

13 ***Content validity***

14 In the g individual meetings the experts suggested a change in the way the
15 scoring system was laid out and a new wording for the answers of certain items. All
16 experts agreed that the area “preventing pressure ulcers” was under-represented in
17 light of their clinical experiences in caring for persons with SCI and suggested
18 adding 7 more items. The additional items focused on detecting the early-onset of a
19 pressure ulcer by skin palpation, on evaluating the increased risk due to time spent in
20 a wheelchair or certain sport practices, as well as life habits (smoking, nutrition), but
21 also guidelines on how to react to a lingering redness of the skin, or checking PU
22 prevention equipment.

23 Following the experts’ recommendations, the Coordination Committee
24 worked on a new version of the SMnac scale. Three experts validated separately the
25 changes brought to this scale and came up with the revised SMnac scale (**Annex 1**).

1 ***Acceptability study of the revised version***

2 Fifteen patients agreed to be included in the study. Three had to be excluded for
3 insufficient data. The mean age was 56 years, 67% were men.

4 The study showed a good acceptability of the revised SMnac by patients. The
5 questions as well as the scoring system were evaluated as clearly laid-out. There was
6 no misunderstanding of the questionnaire's objectives and the relevance was
7 correctly identified for most persons. Patients did not report any comprehension or
8 interpretation issues regarding the items and scoring system.

9 **Reliability**

10 ***Characteristics of the studied population***

11 We analyzed the data from 138 persons with SCI. The mean age was 45.9
12 years (Range: 19-82, SD = 14.9), 75% were men. The main demographics and
13 clinical characteristics of these patients are summed up in **table 2**.

14 ***Global reproducibility (table 3)***

15 The Intraclass Correlation Coefficient is 0.899 (CI 95%: 0.862; 0.927), thus
16 validating a very good reproducibility according to the Landis and Koch
17 classification.

18 ***Reproducibility by sub-score***

19 The sub-scores reproducibility analysis showed a good reproducibility for all
20 three sub-scores. The reproducibility by investigation center showed a good to very
21 good reproducibility according to the centers. The global reproducibility standard
22 variation per center is acceptable, ranging between 0.864 and 0.989.

23 If we look at the reproducibility analysis by sub-score and by center, it
24 appears that sub-score 3 is the one with the largest reproducibility variation between
25 the different centers (Center 4: 0.626; Center 5: 0.982).

1 ***Reproducibility analysis for each item (table 4)***

2 The reproducibility analysis of each item was computed with the weighted
3 Kappa coefficient. Only one item had a very good reproducibility, 11 items had a
4 good reproducibility and 7 items had a moderate reproducibility.

5 **Discussion**

6 The revised SMnac is a self-administered questionnaire aimed at persons with
7 SCI. It is designed for evaluating their knowledge and is adapted to the latest
8 prevention measure for pressure ulcer prevention in persons with SCI.

9
10 Cross-cultural adaptation was the key element of this study. The guidelines
11 regarding cross-cultural adaptations recommended to conduct an acceptability study
12 on the translated questionnaire, among a sample group of patients(11-12). In our
13 case, the acceptability study was deemed extremely useful, since it yielded several
14 changes taken into account by the Coordination Committee and submitted to medical
15 experts for content validity. Cross-cultural adaptations were made, the experts
16 wanted to highlight the importance of the area “preventing pressure ulcers” by
17 adding 7 items, representing the prevention measures taught in France. Only two
18 items of the original scale were modified and no item was discarded.

19 The global reproducibility of the SMnac is very good (ICC =0.899 (0.862;
20 0.927)). It is similar to the reproducibility of the original SMnac version (9) ,
21 implying that additional items included for the area « preventing pressure ulcers »
22 did not alter its metrological property.

23 The reproducibility per item varies greatly. This suggests that the scale’s
24 relevance lies in the global score and not in the item-per-item interpretation. This is
25 often seen in the literature for questionnaires’ validation.

1 The SMnac good reproducibility was a mandatory pre-requisite for its
2 validation. Further studies are needed to assess the validity and responsiveness to
3 change and thus complete the validation of this questionnaire before it can be used in
4 daily medical practices.

5 **Study limits:**

6 This study had 3 potentials limitations. First of all the subjects recruited for the
7 reproducibility study were persons with a recent spinal cord injury or person re-
8 hospitalized within a PM&R setting. There is a need for caution and maybe even
9 further studies to extrapolate the results to persons with chronic SCI. Furthermore, in
10 the acceptability studies of the pre-final version and the revised version, we did not
11 quantify the time spent filling out the scale. Even though no patients made any
12 comments, it would be justified to explore this notion, especially in persons with
13 quadriplegia. Finally the reproducibility results per center unveiled that Center 4 had
14 an excellent reproducibility in all the studied areas. Since this Center was pretty
15 reluctant to conduct this study we came to the conclusion that these results were
16 suspicious. Even though the overall reproducibility of the questionnaire is very good
17 without Center 4, we decided to exclude this center from the other validation stages.
18 To conclude, the revised SMnac is a self-administered questionnaire for evaluating
19 the knowledge of persons with SCI and their self-implemented prevention measures .
20 This scale was updated to include the latest clinical practices, including PU
21 therapeutic educational frameworks. Its global reproducibility is very good,
22 encouraging us look forward to validating the scale through further studies on
23 validity and responsiveness to change.

24

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6

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