



Short Information

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1. Description and use

- NAPPA (Nail Assessment in Psoriasis and Psoriatic Arthritis) is a modular instrument for the assessment of clinical and patient-reported outcomes in nail psoriasis.
- NAPPA comprises three components:
 - 1) NAPPA-QOL measuring nail-specific quality of life
 - 2) NAPPA-PBI reflecting patient-relevant needs and treatment benefits
 - 3) NAPPA-CLIN recording objective nail status.
- The three components (modules) have been developed and validated on an international basis. Thus, several language versions are available. The modules can be used independently from each other.

2. Scientific rationale

- It has become an international standard to appraise outcomes in medicine based on both objective measurements and subjective evaluation from the patient's perspective. Most authorities for drug licensing and reimbursement require the proof of clinically relevant incremental benefit when a medical intervention is assessed. For this, many national bodies and reimbursement agencies have defined criteria and – in some cases – thresholds for treatment evaluations which need to be met by scientifically sound and valid methods. For example, the German federal joint committee (GBA) and the German Institute for Quality and Efficiency in Medicine (IQWiG) have defined patient-relevant benefits as major criteria of treatment assessments, including improvements in mortality, morbidity, quality of life, and treatment burden.

- According to the German guideline for benefit assessment, in skin diseases like psoriasis and nail psoriasis the outcomes measurement should include both objective skin condition measured by the dermatologist and subjective measurement of disease burden and treatment benefits from the patient perspective. NAPPA has been developed to meet the requirements of national authorities for valid outcomes measurements and to also show maximum feasibility in clinical research and routine use.

3. Development

- The NAPPA development was conducted according to the national and international standards of developing test instruments and outcomes research. All development processes were performed in several countries and languages, thus permitting a cross-cultural adaptive process.
- Major steps in the development were a) an international consensus conference on the needs and features of a nail psoriasis outcomes instrument, b) a scientifically stringent study protocol, c) an international item generation from 120 patients with nail psoriasis, d) an expert panel including patients for item selection and discussion, e) a pilot feasibility study on n=55 patients and f) a final validation study in 6 countries / 6 languages on n=203 patients in routine care.

4. NAPPA description

- NAPPA-QOL is a 20-item nail specific quality of life questionnaire which assesses specific quality of life conditions in the past week. Answers are given in Likert scales from 0 to 4. Factor analysis revealed three scales named 'Signs' (nail status), 'Stigma' (nail impact: stigma and emotional status), and 'Everyday life' (nail impact: everyday life). For use in clinical trials, a global score including all items without weighting is used and mean values are determined.
- NAPPA-PBI is a 24-item questionnaire which assesses patient-defined needs before and patient-rated benefits after treatment. The answers are given in Likert scales from 0 to 4, and a global score is calculated based on the importance-weighted benefit items. The principle of PBI is an advanced mode of goal attainment scaling with standardized goal items.
- NAPPA-CLIN has been developed from the NAPSI score, a nail psoriasis-specific score, which in its original version comprises the assessment of matrix and nail bed involvement in every finger and toe by 8 criteria for each nail. The NAPPA-CLIN is a simplified version of the NAPSI which only assesses the least and the worst involved nail of both hands, or both feet, respectively. Thus, the NAPPA-CLIN scores for hands or feet range from 0 to 16 empirically.

5. Languages

- The NAPPA-PBI and NAPPA-QOL have been translated in a validated manner from German (for Germany) to Czech (Czechia), Danish (Denmark), Dutch (Belgium), English (Australia), English (UK), English (USA), French (Belgium), Greek (Greece), Italian (Italy), Japanese (Japan), Polish (Poland), Portuguese (Brazil), Portuguese (Portugal), Spanish (Spain) and Spanish (USA).

- Validation data from the final validation study are available for NAPPA-PBI and NAPPA-QOL in German (Germany), English (USA), Danish (Denmark), Japanese (Japan), Italian (Italy), and Spanish (Spain).
- The NAPPA-CLIN is available in German and English.

6. Instructions

- The NAPPA-QOL and NAPPA-PBI questionnaires are filled in by the patient himself. The questionnaire is self-explanatory; yet, patients can be supported if they are not able to fill it in by themselves. In this case, the support needs to be documented.
- If the NAPPA-PBI is used in an interventional study where the treatment of each patient is known, the following section on current treatment in part 2 may be deleted:

"Please state the type of treatment for nail psoriasis (hands and/or feet) you are currently undergoing (or underwent over the last 12 months): Treatment: ___ Since when?: ___ No treatment of the nail psoriasis over the last 12 months (→ please continue on the next page!)"

- NAPPA-CLIN is filled by the dermatologist or assisting persons. This part needs a basic understanding of clinical signs at the nails.
- If there is a finger and/or toe nail which is not affected at all, this nail should be chosen as the 'the least affected finger' or 'the least affected toe', respectively; in the NAPPA-CLIN.
- In case more than one finger (toe) is least (worst) affected, the severity of nail psoriasis in one of these nails should be documented. For example, if both index finger and ring finger are completely unaffected, the score 0 should be documented for either index or ring finger according to the physician's choice (because this choice will not have an effect on analysis - the value will be 0 in either case).
- If the NAPPA-CLIN is assessed more than once in the same patients (longitudinal study), the nails that are least and worst affected are chosen anew at each assessment. In other words, different fingers/toes may be rated at different time points if the least/worst affected nail is not the same at both time points.

7. Data entry

- The data of NAPPA-QOL and NAPPA-PBI are coded with numbers (0 to 4; "does/did not apply to me" = 5; missing value = -9) and are entered into a spread sheet (e.g. Excel) or statistics program (e.g., SPSS). The spread sheet matrix should be structured as follows: Each row corresponds with one patient and each column corresponds with one variable (=item). The response "currently not in a relationship" in item 13 is scored as missing.
- If an item is answered with two or more "x" or by ticking between two checkboxes, it is treated as missing.

8. Data analysis of NAPPA-QOL

- The NAPPA-QOL global score is computed by averaging all items. In case more than 25% of the items are missing (5 or more items missing), the score is not computed for the respective patient.
- The NAPPA-QOL subscales are computed by averaging the respective items. In case more than 25% of the respective items are missing, the score is not computed for the respective patient.
- The three subscales are comprised of the following items:

'Signs' (nail status):

- 3) Reduced strength of nails (e.g. brittle, thin, atrophied or coming off)
- 4) Symptoms such as hardened, thickened or raised nails
- 5) Changed appearance of your nails
- 7) How different do your nails now look?
- 8) My nail psoriasis makes care of my nails difficult
- 9) I often catch my nails on things

'Stigma' (nail impact: stigma and emotional status):

- 14) I avoid touching other people because of the nail psoriasis.
- 15) I try to hide my nails.
- 16) I am embarrassed by the way my nails look.
- 17) My nails look ugly.
- 18) I have the feeling that other people react negatively to me because of my nail psoriasis.
- 19) I have the feeling that other people stare at my nails.
- 20) I feel depressed or less self-confident due to the nail psoriasis.

'Everyday life' (nail impact: everyday life):

- 1) Itchy fingers/toes
- 2) Pain or other abnormal sensations in the finger/toes
- 6) Difficulty in gripping things
- 10) My nail psoriasis makes working with my hands difficult
- 11) I cannot lead a normal working life because of my nail psoriasis.
- 12) My leisure and sports activities are restricted by my nail psoriasis.
- 13) Nail psoriasis is a burden on my relationship. Or: O currently not in a relationship.

9. Data analysis of NAPPA-PBI

- The weighted NAPPA-PBI global score is computed as follows: For score calculation, both "does not apply" and "question unanswered" will be treated as missing values. The global score will be calculated using all items pairs (importance + benefit) for which the patient has given a response other than "does not apply". Each benefit item is multiplied with the respective importance item, and the product is divided by the sum of all importance items. The results are summed up over all items. The resulting global score ranges from 0 (no benefit) to 4 (highest possible benefit). Only if more than 25% of items pairs are unanswered (=5 or more item pairs with missing values), no global score will be calculated.

10. Psychometric properties

Please refer to the publication of the NAPPA validation study:

Augustin M, Blome C, Costanzo A, Dauden E, Ferrandiz C, Girolomoni G, Gniadecki R, Iversen L, Menter A, Michaelis-Wittern K, Morita A, Nakagawa H, Reich K (2014). Nail Assessment in psoriasis and psoriatic arthritis (NAPPA): development and validation of a tool for assessment of nail psoriasis outcomes. Br J Dermatol 170:591-8

11. Publications

Augustin M, Blome C, Costanzo A, Dauden E, Ferrandiz C, Girolomoni G, Gniadecki R, Iversen L, Menter A, Michaelis-Wittern K, Morita A, Nakagawa H, Reich K (2014). Nail Assessment in psoriasis and psoriatic arthritis (NAPPA): development and validation of a tool for assessment of nail psoriasis outcomes. Br J Dermatol 170:591-8

Blome C, Costanzo A, Dauden E, Ferrandiz C, Girolomoni G, Gniadecki R, Iversen L, Menter A, Michaelis-Wittern K, Morita A, Nakagawa H, Reich K, Augustin M (2016). Patient-relevant Needs and Treatment Goals in Nail Psoriasis. Qual Life Res 25(5), 1179-88

12. Contact and license information

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