BAASIS

The Basel Assessment of Adherence to immunoSuppressive medIcations Scale©

Version 25.07.2023

Basel Assessment of Adherence to Immunosuppressive Medications Scale (BAASIS©) – *EXPLANATION*

The Basel Assessment of Adherence to Immunosuppressive Medication Scale (BAASIS©) was developed to assess adherence to immunosuppressive drugs in adult and adolescent transplant recipients. The BAASIS© can also be easily adapted to assess medication adherence in other chronically ill patient populations. This can be done by replacing 'anti-rejection medications' by 'medications' or a specific name of drug or drug class under study.

As a validated measure of medication adherence, the BAASIS© is listed as a valuable instrument for use in clinical practice and research projects in transplantation or other patient populations (Cleemput et al., 2007; Dobbels et al., 2010; De Geest et al., 2020). The BAASIS© is recommended in the COMMIT transplant guidelines (Neuberger et al., 2017) as a medication adherence self-report instrument, meeting the need for the use of patient-reported outcomes in research to improve patient outcomes (Tong et al., 2022). The BAASIS© psychometric properties have been assessed in transplant populations (Denhaerynck et al., 2023) *(see also below)*.

BAASIS© items have been integrated within the nation-wide prospective Swiss Transplant Cohort Study, thereby demonstrating its applicability in large system-wide multi-centre studies (De Geest et al., 2014). Real-world use of the BAASIS© was demonstrated by Gustavsen et al. (2019) as a measure for annual routine capture of adherence data in renal transplant recipients. The BAASIS© has been integrated in clinical settings worldwide to assess medication adherence in routine practice.

Conceptual basis of the BAASIS©

The BAASIS© follows the taxonomy of medication adherence (Vrijens et al., 2012) which defines adherence as *"the process by which patients take their medication as prescribed"*. This taxonomy indicates that adherence consists of 3 quantifiable phases: *initiation, implementation and persistence*" (see Figure 1).

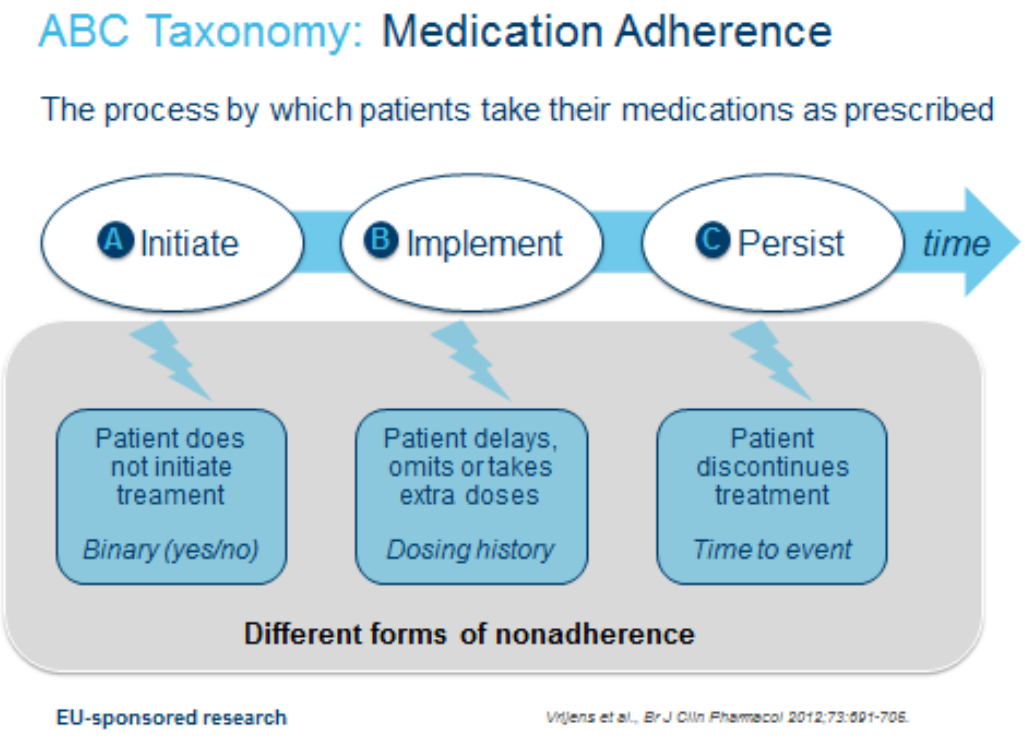

Figure 1: The ABC taxonomy for describing and defining adherence to medications (Vrijens et al., 2012)

- *Initiation* starts when a patient takes his/her first dose of medication. This is a binary event (yes/no).
- *Implementation* of the dosing regimen refers to "the extent to which a patient's actual dosing corresponds to the prescribed dosing regimen, from initiation until the last dose is taken" and implies a dosing history.
- *Discontinuation* refers to "the moment that the patient discontinues his/her medication regimen" and is assessed as a time to event. *Persistence* is thus the duration between time of initiation and the moment the last dose is taken.

NON-ADHERENCE TO MEDICATIONS refers to those situations when issues with *initiation* (i.e. not redeeming a prescription or not starting to take the medication), *implementation* (e.g., dose not taken, problems with timing of medication intake, missing consecutive doses of medication, dose reduction) or *persistence* (i.e., stopping medication intake completely on own initiative) occur.

The latest version of the BAASIS© (2020 and beyond) assesses all three 3 phases of medication adherence as conceptualized by the ABC taxonomy:

- initiation *(item 5 (new since 2020))***

- implementation (items 1A, 1B, 2, 3)

- persistence (item 4).

Initiation

Initiation is assessed via 1 item with a YES/NO answer (*item 5 – last item in the BAASIS©)*.

Patients have to indicate first whether any new medication has been prescribed in the past year (YES/NO). If so, they are asked to answer the initiation item (YES/NO).

Implementation

The implementation phase is assessed via 4 items (Items 1a, 1b, 2 and 3). Each focuses on a different aspect of medication taking: respectively, taking; drug holidays; timing or regularity of medication intake; and dose reduction. All items start with a YES/NO question. For items 1a, 1b and 2, if the patient answers "YES", this is followed by five response categories to document the frequency of implementation problems, i.e., once, twice, 3 times, 4 times and more than 4 times.

The BAASIS© can also be used to assess different types of implementation issues separately (e.g., issues with taking, timing, drug holidays and/or dose reduction).

Persistence / Discontinuation

Persistence / discontinuation is assessed by 1 item (Item 4) with a YES/NO answer.

BAASIS© Versions

There are two versions of the *BAASIS©:*

1. *The 'BAASIS© Interview (self-report)' (recommended),* which is completed as an interview between the healthcare professional and the transplant recipient.

2. The *'BAASIS© Written self-report', which* can be completed by transplant recipients on their own.

We recommend using the '*BAASIS© Interview (self-report)',* as the interview approach provides a more information-intensive data collection approach and more effectively supports a truthful answer pattern.

Both versions of the BAASIS© (*'BAASIS© Interview (self-report)' and 'BAASIS© Written self-report')* consist of the same items, although they are worded slightly differently depending on how they are completed (i.e., interview or written format).

BAASIS© Interview (self-report)

The '*BAASIS© interview (self-report)*' should be conducted in a non-threatening, non-judgmental manner to encourage patients to provide truthful answers (e.g., "*Most patients have difficulties taking their medications correctly. We would be surprised if this never happened to you…*").

The '*BAASIS© interview (self-report)'* begins with a table that should be completed by the healthcare professional/interviewer and the patient together, documenting which (immunosuppressive) medications the patient is currently taking, how many tablets/pills

of each medication, and at what time the patient takes the medication in his daily life (this can deviate from the times prescribed by the clinician). This is to encourage recipients to take all (immunosuppressive) medications into account when answering the questions, while helping the interviewer to personalize the questions.

BAASIS© Written self-report

The *'BAASIS© Written self-report'* is self-explanatory and can be given to recipients to complete on their own. The items are simplified versions of those described for the '*BAASIS© interview (self-report)'* above. No medication table is included in the '*BAASIS© written self-report'.*

Translations of the BAASIS©

The 2021 BAASIS© version has been translated into Arabic, Brazilian Portuguese, Chinese (simplified), Czech, Dutch, French, German, Italian, Japanese, Korean, Norwegian, Spanish and Swedish by native speakers using a forward-backward translation approach based on standard translation protocols (e.g. ISPOR translation guidelines – Wild et al. 2005).

Chinese (traditional), Danish, Haitian Creole, Hebrew, Latvian, Polish, Thai, Turkish, Persian and Urdu translations are currently in preparation.

Please contact us for further translation requests.

How to score the BAASIS©?

The scoring of the BAASIS© (in view of the *initiation, implementation* and *persistence phases of medication* adherence) is explained below.

Initiation

If a patient indicates having been prescribed a new drug (i.e. is answering "YES" to the 1st part of item 5) and then answers "NO" on the second part of item 5, non-initiation of the prescribed medication is identified for this patient.

The proportion of a sample showing non-initiation is calculated only on patients reporting to have been prescribed a new drug.

Implementation

Any YES on any of items 1a, 1B, 2 or 3 indicates an issue with implementation.

The BAASIS© can also be used to assess different types of implementation issues (e.g., issues with taking, timing, drug holidays and/or dose reduction) separately by calculating the proportion of patients scoring YES for each of these items.

Persistence

"YES" on item 4 indicates non-persistence of immunosuppressive medication use.

Psychometric properties of the BAASIS©

The BAASIS© has been analysed psychometrically in **a meta-analysis of individual patient data** (Denhaerynck et al., 2023; *commentary:* Elias et al., 2023) and other studies showing its validity (Tielen, 2016; Haupenthal et al. work in progress, University Hospital Vienna, Austria, Research Group Professor Dr. Gregor Bond).

The meta-analysis of Denhaerynck et al. (2013) included total of **12109 transplant recipients included in 26 studies.** Twenty of 26 studies provided individual participant data (n=11474 recipients). Three validity aspects of the BAASIS©'s implementation scoring were examined: *1) relationships with other variables* (i.e., electronic medication monitoring, other self-report instruments, tacrolimus blood level variability, collateral report by clinicians, self-reported depressive symptoms, self-reported psycho-behavioural constructs and adherence-enhancing interventions); *2) response processes*; and *3) internal structure*. *Reliability* was examined by testing scoring stability over time. 4) *Predictive validity* was assessed by Tielen et al (2016) and Haupenthal et al. (work in progress, University Hospital Vienna, Austria, Research Group Professor Dr. Gregor Bond). Findings on validity are presented below.

1) relationships with other variables

Testing of the relationships with the above-mentioned variables showed that non-adherence assessed with the BAASIS© was significantly associated with: electronically monitored non-adherence (p<.03); other self- and collaterally-reported non-adherence (p<.0001); higher variability in tacrolimus concentrations (p=.02); higher barriers (p<.0001); lower self-efficacy (p<.0001); lower intention (p<.0001); and higher worries (p=.02). Non-adherence also decreased after regimen change interventions (p=.03) (Denhaerynck et al., 2023).

2) response processes

Evaluation of response processes indicated good readability and slightly higher non-adherence with the written version (Denhaerynck et al., 2023).

3) internal structure / Reliability

Structurally (3), the two items on medication taking and its correct timing correlated. Furthermore, about half of the variability in scoring over time could be attributed to the recipients, indicating that the BAASIS© captures more than merely measurement error (Denhaerynck et al., 2023)

4) *predictive validity*

A sample of kidney transplant recipients (Tielen, 2014), followed up prospectively (Tielen, 2016) supported the overall **predictive validity of the BAASIS©** regarding graft loss, as non-adherence to the immunosuppressive regimen shortly after transplantation predicted graft loss two years later.

Haupenthal et al. (work in progress, University Hospital Vienna, Austria, Research Group Professor Dr. Gregor Bond) showed the predictive validity of repeated medication adherence assessments with the BAASIS© over the first two years after renal transplantation in view of allograft rejections.

Summarized, psychometric analyses indicate good validity and reliability of the BAASIS© as a self-report instrument to assess medication non-adherence in transplantation. Thus far only the implementation and (to a lesser extent) persistence phases were evaluated. No psychometric evaluation on the initiation phase (which was added in the 2020 and beyond BAASIS© versions) is currently available.

Language-specific validation studies were performed in Brazilian-Portuguese and Japanese. The Brazilian-Portuguese BAASIS© (BAASIS© version <2020 without initiation item), demonstrating concurrent validity with another self-report instrument (Marsicano et al., 2013), and in Japanese kidney transplant recipients, where its validity was supported by comparison with another self-report instrument and electronic medication monitoring (Kosoku et al., 2023).

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All projects receiving permission to use the BAASIS© are required to send information regarding the publication of their work to baasis-nursing@unibas.ch and will be invited to participate in ongoing validation studies.

Publishing medication adherence findings

For the reporting of medication adherence studies, we advise researchers to follow the ESPACOMP Medication Adherence Reporting Guideline (EMERGE), which is designed specifically to report medication adherence research. EMERGE also builds on the ABC taxonomy that is the conceptual basis of the BAASIS© (see De Geest et al., 2018). A copy of the EMERGE guidelines is sent alongside this copy of the BAASIS© explanations.

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Adaptations of BAASIS guidelines

Version 15.8.2020: Addition of initiation item to BAASIS in BAASIS and explanation of BAASIS

Version 9.2.2021: Adaptation of BAASIS explanation regarding scoring of *initiation item* (Initiation item was added to BAASIS on 15.8.2020 – see above).

Version 4.8.2022: updated translations, references of BAASIS papers

Version 11.2.2023: Psychometrics BAASIS meta analysis on patient level data

Version 10.07.2023: updated language versions and new email address