Assessment of adherence to medication for cardiovascular diseases: measurement tools
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Abstract
The effectiveness of treatment and prevention of chronic illnesses can be optimised with adherence to medication treatment. This is very often assessed by means of a self-report. However, the challenge here is to choose the most suitable questionnaire or the one that is best overall in a given situation. The aim of this systematic review was to assess existing self-reported medication adherence scales, which measure adherence to treatment for cardiovascular disease. The review demonstrated that relatively few disease-specific adherence scales exist. Generic questionnaires and those specific to adherence to hypertension treatment are the most numerous. Questionnaires specifically measuring adherence to antihaemorrhage treatment for atrial fibrillation are particularly necessary and noticeably absent. The two most important aspects that need to be taken into account when selecting the most appropriate scale in a given context are the subject of the measurement (what) and the method of validation (how).

Keywords: adherence, cardiovascular disease, questionnaires, measurement

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Adherence measures for cardiovascular patients
Adherence to treatment is essential to a treatment’s effectiveness. The identification of non-adherent patients and of factors that contribute to non-adherence remains a fundamental challenge for treatment teams providing care to cardiovascular patients. Understanding the causes of non-adherence will enable the development of multidisciplinary intervention programmes focused on promoting healthy behaviours, knowledge and treatment adherence.1

The World Health Organisation (WHO) estimates that only one in two patients complies with the treatment prescribed. Non-adherence typically involves taking lower or higher doses, temporarily or permanently discontinuing treatment, and simultaneously taking over-the-counter medication. Factors that contribute to lower pharmaceutical adherence include: old age, cognitive impairment, physical disability, depression, lack of social support, poor socio-economic standing, co-morbidities, drug interactions and adverse effects, long duration of treatment, polypharmacy, a large number of doses to be taken within a single day, and poorly functioning healthcare systems.2

The term adherence is used to describe the extent to which a patient follows medical advice, which includes taking the medication as prescribed. Adherence is understood as the patient’s informed and voluntary involvement in the accepted treatment process. This definition implies an empowerment of the patient, who agrees with the physician on the treatment objectives (concordance). Therefore, treatment adherence means that the patient takes the medication as prescribed, and does not interrupt the treatment out of an unwillingness to continue. The definition of adherence includes two aspects: one is the intensity of involvement in following the recommendations; the other is persisting with compliant behaviour throughout the treatment period.3

Areas of special interest in cardiovascular treatment include chronic treatment for hypertension and heart failure, and anticoagulation treatment for atrial fibrillation, due to the increasing incidence of these problems in the population, especially among the elderly.

Non-adherence to treatment is the most common reason for poor blood pressure (BP) control in hypertensive patients. Despite advances in pharmaceutical treatment for hypertension, epidemiological studies in Poland have demonstrated that the primary factor contributing to an unsatisfactory response to pharmaceutical treatment is poor compliance/adherence. Approximately 40 to 60% of hypertensive patients do not comply with the prescribed treatment.4

Atrial fibrillation (AF) mainly affects elderly individuals (3.7–4.2% of patients aged 60–70 years, and 10–17% of those aged 80 and above). In the treatment of AF, adherence to anticoagulant treatment in elderly patients is a significant challenge. On one hand, oral anticoagulants decrease the risk of an ischaemic stroke, but on the other, they increase the risk of haemorrhaging. Available data show that between 10 and 26% of patients discontinue warfarin treatment within the first year of treatment. The data also suggest that, alarmingly, as few as 50% of patients succeed in maintaining target INR values over the

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course of treatment, and as many as 22–33% of patients newly prescribed preventative anticoagulants discontinue the treatment within the first year. Similar challenges exist in the treatment of heart failure (HF), which affects 10–20% of the population over 60 years of age. One in five patients hospitalised for HF is rehospitalised within the first month after discharge, and one in three within the next two months; 80% of HF hospitalisations are rehospitalisations due to exacerbation of symptoms. Statistics on one- and five-year mortality rates from HF reveal similar findings. One significant cause of rehospitalisation is non-adherence to treatment.

### Adherence measurement methods

Adherence measurement methods can be broadly defined in two categories: direct and indirect. Direct methods include electronic monitoring systems, pill counting, and measurement of medication use, drug concentrations in bodily fluids and serum activity of selected biochemical markers present in the medication.

Indirect methods include surveying and observation, with discussions regarding the way in which the prescribed medication is taken. Indirect observation methods commonly include subjective measures, such as self-reported questionnaires and scales. Apart from pharmaceutical adherence, many of these methods also help identify difficulties in taking medication, patients’ beliefs and attitudes towards the treatment, or their knowledge of the disease and its treatment. Adherence questionnaires can be generic, that is, suitable for the assessment of adherence in a variety of chronic diseases, or they can be disease-specific.

Self-reported questionnaires are an alternative to other measures, although they have a number of potential limitations related to, for example, the patients’ understanding of the questions and willingness to provide answers, which may affect the results. The choice of questionnaire is also dependent on the availability of a version adapted to a given national setting. Some questionnaires only measure pharmaceutical adherence, while others allow researchers to evaluate the entire treatment process.

Despite the risk of overestimating patient adherence or non-adherence, the use of questionnaires is the cheapest and simplest method, which also provides additional information on the causes of non-adherence. Most questionnaires capture data on medication dosage from the start of treatment, throughout the treatment period, and up to the end of treatment.

In 2014, 43 adherence scales were described, which can be grouped into five categories, evaluating: (1) medication adherence only, (2) medication adherence and barriers to adherence, (3) barriers to adherence only, (4) patient beliefs about adherence only, and (5) patient beliefs and barriers to adherence. Despite the relatively large number of questionnaires available, no gold standard for adherence measurement has been established.

The purpose of this article was to review the validated instruments available for measuring adherence to treatment in selected cardiovascular diseases, identify the ones that are most commonly used, and offer the best psychometric properties. We chose to focus on hypertension, atrial fibrillation and heart failure due to their increasing epidemiology and the fact that the data from the literature show a high level of non-adherence.

At present, none of the available methods can be considered a gold standard for adherence assessment. There are many questionnaires available in the medical databases, but the selection of a method to monitor adherence should be based on the individual attributes and goals/resources of the study or the clinical setting. We chose the ones that are most commonly used in research.

### Adherence measures applicable to hypertension

The Morisky Medication Adherence Scale is the most commonly used questionnaire worldwide. Its original version, developed by Morisky, Green and Levine (MGL) in 1986, comprised four items and evaluated adherence to medication in hypertensive patients. The original questionnaire had only satisfactory psychometric properties (alpha reliability = 0.61).

The scale was translated into Portuguese and tested on hypertensive patients, showing satisfactory psychometric properties as an instrument for adherence measurement (alpha reliability = 0.73). Another attempt to adapt it, for patients at risk of atherosclerosis, showed the scale could be useful in evaluating non-adherence and its causes, but not in elderly patients (Cronbach’s α = 0.47, internal correlations 0.11–0.26). The MGL questionnaire was used for adherence measurement in a number of chronic diseases: asthma, chronic obstructive pulmonary disease (COPD), diabetes, tuberculosis, leukaemias and kidney failure; and with a number of treatments: immune treatment for allergies and hay fever, and treatment with calcium, vitamin D, acenocoumarol and others.

In 2008, the eight-item Morisky Medication Adherence Scale (MMAS-8) was developed, adding four items related to the circumstances of adherence to the previous four-item MGL test. The cultural adaptation of the questionnaire into Polish and its validation showed that the adapted questionnaire had good psychometric properties (Cronbach’s α = 0.808), similar to the original (Cronbach’s α = 0.83). The questionnaire has also been translated and adapted into French (Cronbach’s α = 0.54), Thai (Cronbach’s α = 0.61), Farsi (Cronbach’s α = 0.697) and Brazilian Portuguese (Cronbach’s α = 0.682).

Based on the criteria used, the usefulness of the MMAS as a source of information on BP control in clinical settings was confirmed. There was a significant correlation between the adherence scale and BP control (χ² = 6.6; p < 0.05). High adherence of the patients studied was expressed as a score of 8, medium adherence from 6 to < 8 and low adherence < 6. The scale comprising eight items proved to be a reliable instrument (α = 0.83), which significantly correlated with BP control (p < 0.05).

Another commonly used adherence measure is the Hill–Bone Compliance to High Blood Pressure Therapy Scale, which comprises items related to both medication adherence in hypertension, and lifestyle modifications. Its purpose is to assess behaviours centred around taking medication, dietary sodium restriction, and regular follow ups among hypertensive patients. In its Polish version, the Hill–Bone scale showed very good psychometric properties with regard to reliability, validity and acceptability. The Cronbach’s α for the Polish version was 0.851, similar to the original (0.74), and to other adapted versions: Turkish (0.72), South African (0.77), Malaysian (0.64) and German (0.73). Relevant studies demonstrated that the Hill–Bone questionnaire is a valid and reliable instrument for...
measuring adherence to hypertension treatment, which allows for the assessment of self-reported compliance in patients and therefore for planning adequate treatment.14,15

The Treatment Adherence Questionnaire for Patients with Hypertension (TAQPH) is a scale developed in 2011, comprising 28 items evaluating six adherence domains: pharmaceutical treatment (nine items), diet (nine items), exercise (two items), stimulation (three items), weight control (two items) and coping with stress (three items). Answers are provided using a four-item Likert scale and the total score is between 28 and 112. Higher scores indicate better adherence. The Cronbach’s α for the entire questionnaire was 0.86 and 0.82, indicating good psychometric properties.17 The questionnaire has been translated into Farsi, and subsequent validation demonstrated its good psychometric properties (α = 0.80) and strong correlation with the Morisky scale (p = 0.27).

The Brief Medication Questionnaire (BMQ) is likely to be the oldest available questionnaire measuring adherence to treatment and barriers to adherence. Its authors intended to develop a simple but sensitive and accurate instrument for identifying causes of non-adherence, also in patients treated with multiple medications. The questionnaire comprises five items related to medication-taking in the two preceding weeks, the perceived effectiveness of the treatment, any inconvenience it causes, and possible difficulties related to the treatment and its dosage. It is composed of three different screens. The first one, a five-item regime screen, assesses medication-taking in the preceding week; the two-item belief screen assesses the effectiveness of the drug and any inconveniences experienced by the patient, and, finally, the two-item recall screen assesses problems the patients faced with regard to remembering their medication.18

The Compliance of Hypertensive Patients Scale (CHPS) was developed by Lahdenperä et al.19 to provide information regarding patients’ intentions, responsibility and co-operation with regard to treatment adherence. The items are grouped into five subscales: lifestyle, intention, attitude, responsibility and smoking. Inter-item correlations and corrected item total correlations across subscales are 0.24–0.61 and 0.32–0.67, respectively. With regard to the theta coefficient, good internal consistency was observed. The scale has not been used by other authors.19

The Facilitators of and Barriers to Adherence to Hypertension Treatment Scale (FATS) is an 18-item scale evaluating beliefs related to treatment and causes of adherence and non-adherence to treatment. The authors’ aim was to develop a culturally sensitive measure of barriers to hypertension treatment adherence in African and black American women. Qualitative studies performed in hypertensive patients suggest three categories of factors associated with adherence to hypertension treatment: beliefs about hypertension, facilitators of adherence, and barriers to adherence. The questionnaire comprises four subscales: social support, knowledge on hypertension, self-care and adherence-enhancing behaviours, and barriers to adherence. The α coefficient for the 18-item FATS was 0.78.

Regarding the multivariate regression model, which was the control for the blood pressure stage, it revealed that the FATS significantly correlated with the Hill–Bone High Blood Pressure Compliance Scale (standardised β = 0.35; p = 0.0014). The questionnaire was only used by the authors of the original version.20

The Self-efficacy for Appropriate Medication Use Scale (SEAMS) was developed for use in low-literacy patients. Its psychometric properties were tested on 436 patients hospitalised for ischaemic heart disease and other cardiovascular diseases, including hypertension. Its reliability was evaluated by measuring internal consistency and test–retest reliability. Reliability and validity analyses were also performed separately among patients with low and higher literacy levels. The initial 21-item scale was ultimately reduced to 13 items. Internal consistency reliability of the instrument is good: alpha reliability is 0.89 in low-literacy populations and 0.88 in populations displaying high literacy. (Responses are scaled with the use of a three-item Likert scale, with 1, not confident; 2, somewhat confident; and 3, very confident. It was found that 52.3% of the variance was explained by a two-factor solution.

The scale’s effectiveness proved to be similar with different levels of literacy, which suggests that the instrument can be used with patients whose literacy skills are not at a high level.22 With its high level of reliability and validity, the SEAMS is an appropriate tool to assess self-efficacy for medication use in patients suffering from chronic diseases.

Adherence measures applicable to AF

The available publications on AF mainly focus on adjustment to anticoagulant therapy. A review of reports that have been published on the evaluation of adherence to treatment in AF showed the Morisky Medication Adherence Scale, described above, to be the most commonly used adherence questionnaire in this area as well. Studies by Patel et al.23 and Jankowska-Polańska et al.24 used the eight-item version for measuring adherence to anticoagulant therapy, while the study by Castellucci et al.25 used the four-item version.

Published reports on adherence to treatment for AF most commonly use other adherence measures.25 These are the population’s medication possession ratio (MPR) and the proportion of days covered (PDC).26-28 In this context, adherence was defined as an MPR or PDC ≥ 0.8. In most cases MPR and PDC are expressed as percentages of the time to which the medication pertains. MPR is the sum of the days’ supply for all fills of a given drug in a particular time period, divided by the number of days in the time period:

$$\text{MPR} = \frac{\text{Sum of days’ supply for all fills in period}}{\text{Number of days in period}} \times 100\%$$

Compared to MPR, PDC is a more conservative estimate of adherence. The two have a similar formula, but PDC focuses on ‘coverage’ rather than days of supply:

$$\text{PDC} = \frac{\text{Number of days in period ‘covered’}}{\text{Number of days in period}} \times 100\%$$

Studies on adherence to anticoagulant treatment in atrial fibrillation commonly use scales of satisfaction with anticoagulant treatment. The Anti-Clot Treatment Scale (ACTS) is one of the most commonly used patient-reported scales. It is a 15-item scale, comprising a 12-item burdens scale and a three-item benefits scale. The ACTS burdens items use a five-point Likert scale, where 1 is the rating for ‘extremely’ and 5 is for ‘not at all’.

In contrast to the reverse-coded ACTS burdens, the highest score on the ACTS benefits (scale from 1 to 5) indicates that the
patient is extremely satisfied with the treatment administered. The ACTS burdens and the benefits scores are obtained after summing up the scores from the 12 and three items, respectively. The range of the former is 12–60 and the latter 3–15.

Results of a cross-cultural validation revealed that the item-level and scale-level psychometric criteria were successfully met by both the ACTS burdens and ACTS benefits. There were some slight doubts with regard to the Dutch version of the scales as the reliability criteria had not been met (α=0.72, test–retest intra-class correlation=0.79). Aggregate endorsement frequencies and skewness assessment conducted at an item level indicated that the reduction of response options from five to four might result in an improvement in response scales.35,36

The Duke Anticoagulation Satisfaction Scale (DASS) includes 25 items evaluating the positive and negative effects of anticoagulation: limitations (e.g. limitations on physical activities that might cause bleeding, or restrictions connected with diet), hassles and burdens (e.g. daily and occasional hassles such as remembering to take the medicine and waiting to have blood tests done, respectively), and positive psychological impacts (e.g. reassurance stemming from anticoagulation treatment administration). Answers are given using a seven-item Likert scale.

The psychometric evaluation showed high Cronbach’s alpha coefficients: 0.88 for the overall DASS summary score, 0.78 for the positive-impact sub-scale, 0.91 for the negative-impact sub-scale, 0.87 for the limitations sub-scale, and 0.88 for the hassles sub-scale. The questionnaire has been extensively used with patients with AF or other diseases requiring anticoagulant treatment.37,38 It has been translated into Brazilian Portuguese, and the cultural validation demonstrated very good psychometric properties (Cronbach’s α = 0.79).39

In some studies, the Duke questionnaire was used as a quality-of-life measure, and the authors demonstrated that dissatisfaction with anticoagulant treatment contributed to lower adherence, worse INR control and worse clinical outcomes. The DASS scale is useful in identifying reasons for dissatisfaction with treatment, and in planning and implementing interventions to reduce this dissatisfaction.37,38

The Adherence Barriers Questionnaire (ABQ) comprises 14 items evaluating three groups of factors associated with non-adherence to treatment: intentional factors, unintentional factors, and medication- and healthcare system-related barriers to adherence. All answers are provided using a four-item Likert scale. The authors validated the questionnaire with a group of AF patients, demonstrating the very good psychometric properties of this instrument (Cronbach’s α = 0.820). The structure of the questionnaire makes it suitable for measuring adherence in other diseases.

The Perception of Anticoagulation Treatment Questionnaire (PACT-Q) was developed for evaluating patients’ expectations of and satisfaction with anticoagulant therapy. The original version of the questionnaire comprises 27 items. The PACT-1 section includes seven items evaluating the patients’ expectations with regard to the prescribed anticoagulant treatment and is completed before the treatment starts. The PACT-2 section evaluates three dimensions: convenience of treatment (11 items), burden of disease and treatment (two items), and satisfaction (seven items). Answers are given using a five-item Likert scale.

The questionnaire was developed simultaneously in American English, French and Dutch, and subsequently translated into 11 other languages, including Polish.40 Content validity of DASS and PACT-Q was good, as the scales included dimensions regarded as important by the patients studied: satisfaction (DASS) and treatment satisfaction (PACT-Q), hassles, limitations, burdens (DASS), convenience (PACT-Q) and expectations (PACT-Q).

Adherence measures applicable to HF

One important dimension of HF treatment and care, besides medication, is lifestyle modification, with the focus placed on regular follow ups, restricting fluid and salt intake, and daily weighing. With such treatment plans, measurements are required not only of pharmaceutical adherence, but also of the self-care capabilities of HF patients. Available publications point to questionnaires assessing self-care opportunities, lifestyle changes and pharmacological treatment. The most commonly used questionnaires include the following.

The Self-Care of HF Index (SCHFI, pronounced ‘skiffy’), which was originally named the Self-Management of Heart Failure Scale. Its 2004 version comprised 15 items, grouped into three domains, with a ‘total self-care score’ optionally calculated for the whole questionnaire. Over the years, the questionnaire underwent several modifications. The current version includes 22 items in the following domains: maintenance (10 items), management (six items) and confidence (six items), and the author provides both the questionnaire and instructions for the use of each of the three domains separately on her website. The total score ranges from 0 to 100, with higher scores denoting better adherence. The questionnaire has been translated into a number of languages: Chinese, Italian, Spanish, German, Portuguese, Japanese, French, Slovak and Dutch. Adaptation studies showed that the instrument has good or very good psychometric properties in all three domains, making it useful in practice.41

The European Heart Failure Self-Care Behaviour Scale (EHFScB) was developed for measuring self-care capabilities in terms of adherence to dietary recommendations, pharmaceutical adherence, monitoring and identifying symptoms of exacerbation, and care-seeking behaviour in HF. It was based on Orem’s theoretical framework of self-care. Answers are provided using a five-item scale, from ‘totally agree’ to ‘totally disagree’. Two versions of the questionnaire are available, a nine- and a 12-item one. Scores on the EHFScB-9 range from 9 to 45 and the lower the score, the better the self-care.

The internal consistency of EHFScB was 0.77 (0.71–0.85). Psychometric properties and the content of individual items were subjected to factor analyses and critical evaluation, after which further analysis of EHFScB-9 was conducted. With regard to EHFScB-9 overall, the reliability estimates were 0.80, which is acceptable, whereas Cronbach’s α ranged between 0.68 and 0.87, depending on the country.42 The instrument has successfully passed validation and psychometric evaluation in many populations and cultures, and has undergone multiple translations and adaptations, including one into Polish.43

The Medication Adherence Report Scale (MARS) is a self-reported questionnaire used for evaluating adherence to treatment in the case of chronic disease. The questionnaire has been used in patients with COPD, asthma, chronic cancer pain, colitis and heart failure.44 The respondents use a five-item
Likert scale, from five (never) to one (always). The questionnaire makes it possible to calculate total adherence scores and to classify patients into two dichotomous groups: high (> 23) and low adherence (< 22). The maximum score, 25 points, indicates perfect adherence.

The Revised HF Compliance Scale evaluates adherence to recommendations regarding dietary patterns, such as sodium restriction and fluid restriction, physical activity and daily weighting. Answers are provided using a five-point scale, with 0 signifying never; 1 = seldom; 2 = half of the time; 3 = mostly; 4 = always. Compliance is measured based on the patients’ answers regarding the preceding week (sodium and fluid restriction, medication and physical activity), the preceding month (daily weighting), or the last three months (appointment keeping) before index hospitalisation.

Compliant patients are those who answer ‘always’ or ‘mostly’ with regard to following particular recommendations and perform daily weighing or monitor their weight at least three times a week. If the patients successfully follow at least four out of the six recommendations, they are regarded as ‘overall compliant’. The questionnaire has good psychometric properties: Cronbach’s α = 0.768, average inter-item correlation: 0.362. In available studies, the questionnaire has been used both for measuring overall compliance and for evaluating the specific components. A Polish version is currently being developed.

In Cameron’s meta-analysis to identify instruments that measure self-care in chronic heart failure (CHF) and to demonstrate their psychometric properties, out of 14 scales measuring self-care capabilities in HF, only two disease-specific self-care instruments had been subjected to stringent psychometric testing among patients with CHF [the Self-care Heart Failure Index (SCHFI) and the European Heart Failure Self-care Behavior Scale (EHF/ScBS)]. Therefore knowledge about CHF self-care and CHF clinical practice can only be advanced if researchers use these scales in their studies.46

Authors studying adherence to HF treatment often use the so-called Medication Event Monitoring System (MEMS). The system consists of a micro-electronic monitoring device, fitted in the caps of medication containers, which records the number of container openings. Such data allow the calculation of medication adherence. The number of days on which the prescribed number of doses was taken during the monitoring period is divided by the total number of days during the study period and then multiplied by 100%. A result of a minimum of 88% indicates that the patient adhered to the medication regimen. Any patient with a result below this figure is considered non-adherent. This figure was adopted based on a study that showed that patients who displayed an adherence of over 88% had higher chances of Edmonton Frailty Scale (EFS).46

The Heart Failure Compliance Questionnaire by Evangelista et al. measures compliance in six domains: follow-up appointments, medication, diet, exercise, smoking and stopping alcohol intake. The evaluation period for follow-up appointments is the preceding three months, and for medication, diet restrictions (fluids and sodium), and exercise, the preceding week. The respondents use a five-item Likert scale, from 0 (never) to 4 (always). The total score for each domain is between 0 and 100 points. The total adherence score can also be calculated, with a result of 75% indicating good adherence.46

The Medication Adherence Scale (MAS) originally comprised 32 items and was developed for measuring three groups of factors associated with adherence. The questionnaire was piloted on a group of 10 patients with HF. The number of items was due to the need to evaluate patients’ knowledge, attitudes and barriers related to taking medication. A group of four experts on HF verified the accuracy and completeness of the instrument, and the respondents confirmed their understanding of the items.

The final questionnaire comprises 14 items, providing general information about behaviour with regard to taking medication, and 18 items related to knowledge (three items), attitudes (four items) and barriers (11 items). Patients use an 11-item Likert scale to answer, between 0 (strongly disagree) and 10 (strongly agree). The 14 general items include questions about how many prescriptions for pills the patients have, how many pills they take per day, how many times they need to take pills on different time schedules, how they keep track of the pill times, whether or not they have anybody who helps make their medication schedule, whether or not they use pills for their heart that healthcare providers did not prescribe, whether or not they skip taking some of their pills, how they take their pills when they go out, and whether they have anybody to remind them to take their medication. The above items only serve descriptive purposes and were not part of the psychometric testing.

Regarding the psychometric evaluation, 63% of the variance in medication adherence was explained by three factors, as revealed in the principal component analysis, namely, knowledge, attitudes and barriers to medication adherence. Internal consistency at the sub-scale level was measured with Cronbach’s α, whose range was 0.75–0.94. The Spearman rho correlation coefficients between the MEMS and Knowledge, Attitudes and Barriers scores ranged between 0.25 and 0.31 (p < 0.05).

Conclusion

Effective identification of patients at risk of non-adherence can be particularly useful in planning interventions to improve symptom control, prevent complications, enhance long-term outcomes, and limit adverse effects of treatment. Unfortunately there is no gold standard for adherence measurement. The ideal measurement tool for adherence should be easy to apply, practical, reliable, flexible, user friendly and low cost. Our study should provide general directions to help healthcare professionals choose the most common and suitable questionnaires for their aims and subsequently deliver efficient, tailored interventions to improve patients’ medication-taking behaviours.

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