



Research Article

Development of Collaborative Medication Adherence in Bipolar disorder Questionnaire (C-MABQ)

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Abstract

Purpose: To develop a theory and evidence-based medication adherence questionnaire to identify an individual's modifiable determinants (barriers/facilitators) of adhering to medication for bipolar disorder (BD). **Method:** The questionnaire was developed by generating initial items based on a systematic review of adherence determinants in BD, followed by qualitative work to prioritise them and review by behavioural scientists. The resulting draft Collaborative Medication Adherence in Bipolar disorder Questionnaire. C-MABQv1, was reviewed by healthcare professionals for comprehensiveness and face validity. Their feedback was integrated into a second version, C-MABQv2, which was further refined through cognitive interviews with patients, leading to the final version of C-MABQ. Patients 18 or over diagnosed with BD and prescribed at least one BD medication participated in cognitive interviews. **Results:** Informed by our previous research, we initially formulated 75 items. These were reduced to 51 items (C-MABQv1) following discussion with behavioural science experts. Six healthcare professionals (two psychiatrists, two mental health pharmacists prescribers, two psychiatric nurse prescribers) participated in reviewing C-MABQv1. Similarly, seven patients with BD participated in cognitive interviews of C-MABQv2. The final C-MABQ demonstrated good readability (Flesch-Kincaid score = 66) and face and content validity, supporting its potential to assess individuals' prominent adherence determinants in BD. **Conclusion:** Grounded in theory and evidence, the C-MABQ is a clear, comprehensive and accessible questionnaire designed for people with BD to identify their key determinants of medication nonadherence. Thus, the C-MABQ facilitates personalised interventions by targeting those adherence determinants, offering strong potential to improve outcomes in BD.

Keywords: Adherence; Bipolar disorder; Theoretical Domains Framework; Adherence Questionnaire; Adherence Scale; Adherence Tool; Barriers and facilitators; Behavioural Medicine.

Introduction

Around 40% of patients with bipolar disorder (BD) do not adhere to their prescribed medication regimen, resulting in relapse, hospitalization, increased suicidality, and higher healthcare costs [1-3]. One of the key challenges to successfully addressing non-adherence is identifying an individual's modifiable barriers and facilitators (determinants) of adherence which is critical for providing personalised support. In the scope of this study, we define modifiable determinants as 'any determinants of medication adherence that can be modified by the patient, carer, or prescriber within a short timeframe (days or weeks) to improve adherence'[1]. There is a notable absence of questionnaires to identify individual's adherence determinants in mental health, particularly in BD. Currently available validated adherence questionnaires such as BARS and MARS-5 [4,5] focus on the nature of adherence, e.g., frequency and magnitude, or explore very limited adherence determinants (e.g., medication beliefs, forgetfulness). Additionally, there is an absence of comprehensive behavioural theory underpinning the development of most adherence questionnaires in mental health despite this being critical for subsequent development of any behaviour change intervention [6,7].

Questionnaire development is a systematic process that involves creating a structured set of questions to elicit specific information from respondents. It requires careful attention to questionnaire design principles, such as crafting clear and unbiased questions and choosing appropriate response formats [8,9]. Boateng et al. provides a best practice guideline for developing and validating a questionnaire [10]. It involves nine steps: 1) identification of the domain(s) and item generation, 2) consideration of content validity, 3) pre-testing questions, 4) sampling and survey administration, 5) item reduction, 6) extraction of latent factors, 7) tests of dimensionality, 8) tests of reliability, and 9) tests of validity.

In our prior research, as a part of domain identification, we conducted: I) a systematic review identifying modifiable adherence determinants in bipolar disorder [1] and II) a qualitative study prioritizing these determinants and identifying new ones [11]. This study focussed on item generation, content validity and pre-testing questions.

Generating items requires careful attention to clarity, tone, structure, and readability, as these elements directly influence response quality and the questionnaire's validity. The BRUSO model (Brief, Relevant, Unambiguous, Specific, Objective) [9] provides a useful framework for item design. Visual aspects like font and question order also affect engagement [12,13].

Creating clear questionnaire items from modifiable adherence determinants requires input from various stakeholders to ensure consistent interpretation and understanding. Review by subject matter experts such as healthcare professionals is recommended to assess face and content validity of questionnaires. Face validity refers to whether, on the surface, a questionnaire appears to measure what it is intended to measure. Content validity assesses whether the questionnaire comprehensively covers the full range of concepts it aims to measure [14]. Questionnaire review by 5-7 experts is recommended [10]. Pre-testing questionnaires is a crucial part of questionnaire development. Cognitive interviews assess understanding, information retrieval, and response accuracy. Thus, the goal of stakeholders engagement is to assess face and content validity and to ensure questionnaire's relevance, clarity, and ease of use.

This article describes the development of 'Collaborative Medication Adherence in Bipolar disorder Questionnaire (C-MABQ)', a 50-items adherence questionnaire to identify an individual's adherence determinants. The C-MABQ is grounded in the Theoretical Domains Framework (TDF), a comprehensive behavioural science framework encompassing 14 domains: Knowledge, Skills, Social/ Professional Role and Identity, Beliefs about Capabilities, Optimism, Beliefs about Consequences, Reinforcement, Intentions, Goals, Memory, Attention and Decision Processes, Environmental Context and Resources, Social Influences, Emotion and Behavioural Regulation [15]. Each C-MABQ question is mapped to relevant TDF domain. And each TDF domain is linked to one or more behaviour change techniques. Thus, the C-MABQ aims to facilitate personalised adherence support by identifying each person's specific adherence determinant, allowing interventions to be tailored to their needs.

Methods

Ethical Approval

Ethical and governance approvals were obtained from Cambridgeshire and Hertfordshire Research Ethics Committee (Reference:19/EE/0288) and United Kingdom Health Research Authority (IRAS project ID:261687), respectively.

Informed consent was obtained from all the participants.

C-MABQ Development

The development of C-MABQ involved three steps:

1. initial item formulation and refinement
2. Review by healthcare professionals
3. Cognitive interviews with patients to finalise the questionnaire.

Formulating preliminary items and their refinement

Preliminary items for the C-MABQ were developed by AP, based on previously reported modifiable adherence determinants [11]. To ensure clarity, simplicity and to reduce response bias, item construction followed the BRUSO model emphasising brevity, relevance, unambiguity, specificity, and objectivity [9]. Items avoided jargon, acronyms, complex phrasing, and double-barrelled or negatively worded statements. Where adherence determinants involved multiple concepts (e.g., forgetfulness in administering or collecting medication), separate statements were created. A mix of positively and negatively worded items was included to minimise acquiescence bias.

Design elements such as font style, font size, and item order were carefully considered to enhance readability and engagement. The questionnaire began with a broadly applicable, easy-to-answer item to encourage participation. Items followed a logical sequence, with more sensitive questions placed mid-way to maintain respondent comfort.

These preliminary items were then discussed with behavioural science experts, AD (Psychologist with experience of developing adherence scales), CG (Psychologist with expertise in patient related outcome measures) and DB (behavioural scientist with expertise in medication adherence) in group meetings. We held three separate one to two hours meetings to review each item and response options. Items were refined and consolidated resulting in C-MABQv1 (See Supplementary File I).

Review by healthcare professionals to generate C-MABQv2

C-MABQv1 was then reviewed by healthcare professionals with experience of consulting patients and prescribing medication for bipolar disorder. Healthcare professionals currently working in mental health settings, had at least one year of experience in such settings, and were involved in the frontline care of patients with bipolar disorder were eligible to review. Each healthcare professional participated in a brief phone call to clarify the purpose of the review, followed by completion of a structured feedback form (See Supplementary File II). The form included C-MABQv1 items and prompted feedback on clarity, relevance, item order, and potential omissions of adherence determinants. Content validity was assumed if no additional determinants were suggested or if suggestions were deemed irrelevant or inapplicable by researchers.

Cognitive interviews with patients to generate final C-MABQ

Patients who had a diagnosis of bipolar disorder, prescribed at least one medication for bipolar disorder, and able to provide informed consent were eligible to participate in cognitive interviews. AP conducted cognitive interviews with patients using C-MABQv2.

Consenting patients received C-MABQv2 before the interview. The cognitive interviews aimed to identify difficulties in understanding

or responding to C-MABQv2 items. AP explained the purpose of the interview at the start. Participants read each C-MABQv2 item aloud and responded verbally. AP then asked if they understood the item or found any ambiguity and how they decided their response. Feedback on presentation features (e.g., font style, size, colour) was also sought. Based on the findings, C-MABQv2 was refined to create the final version C-MABQ. Face and content validity were measured subjectively based on responses from patients. C-MABQv2 is considered to have face validity if patients understood and interpreted questions correctly, responded without difficulty, and suggested minimal or no changes during cognitive interviews. Similarly, content validity was considered to have established if no new determinants was identified.

The final C-MABQ was evaluated for word frequency and readability. To ensure clarity and ease of understanding, it is recommended to keep items to 15 words on average and not longer than 25 words [16-18]. Specifically, sentences with 8 words or fewer are very easy to read; 11 words are easy; 14 words are fairly easy; 17 words are standard; 21 words are fairly difficult; 25 words are difficult; and 29 words or more are very difficult [16-18]. These parameters were applied to support comprehension and minimise cognitive load during questionnaire completion. A Flesch-Kincaid reading ease score of 60+ or grade level ≤ 8 (readable by ages 11-12) - recommended for patient materials- indicates good readability and accessibility [19,20].

Results

Development of C-MABQv1

AP formulated 75 statements representing the 50 previously reported and prioritised modifiable determinants of adherence [11]. Multiple statements represented each determinant to allow for variations such as negatively and positively phrased and differences in the vocabulary used to represent the determinant. For example, four statements were generated for the determinant 'Not knowing the risks of stopping medication': I) I am unsure about the risks of stopping my medications. II) I understand very well the risks of stopping my medications. III) I don't know what would happen if I stop taking my medications. IV) I know that I will become unwell if I stop taking my medications.

Following discussion with experts, 51 out of the 75 statements were selected (See supplementary file I). We opted for a five-point Likert scale response format. The items were divided into three sections with following response options:

- 1) Very Easy, Easy, Neutral, Difficult, Very Difficult,
- 2) Strongly Agree, Agree, Neither Agree nor Disagree, Disagree, Strongly Disagree
- 3) Totally Acceptable, Acceptable, Neutral, Unacceptable, Totally Unacceptable

Review by healthcare professionals to evaluate face and content validity

Six healthcare professionals (two psychiatrists, two mental health pharmacist independent prescribers and two psychiatric nurse independent prescribers) were recruited for review of C-MABQv1.

The review informed the following changes to C-MABQv1 statements:

- Response option ‘Neutral’ in section one and ‘Totally Acceptable’ in section three were changed to ‘Neither easy nor difficult’ and ‘Perfectly Acceptable’ respectively.
- ‘Condition’ was changed to mental health condition in statements 8, 9, 16, 39 and 40.
- ‘Healthcare team’ was changed to ‘mental health team’ in statements 4, 17 and 18.
- ‘prescriber’ was changed to ‘mental health team’ in statement 19.
- ‘illness’ was changed to ‘mental health condition’ in statement 20

Further changes to C-MABQv1 are presented in supplementary file III. Apart from the changes suggested, the healthcare professionals agreed that the statements were clear and represented the determinants of adherence.

Although healthcare professionals considered the list of determinants comprehensive, some suggested additional determinants: not liking the effects of their mood being artificially flattened or controlled, low mood, substance misuse, knowing

which medications are for bipolar disorder, being able to talk to the healthcare team about side effects, knowing where to find good quality information about my medications and side effects. However, all of these were either considered to have been addressed (with slightly different wording) or non-modifiable within the context of this study.

Cognitive interviews with patients

Seven patients; four females and three males aged 27 to 69, were recruited for the cognitive interviews. All patients understood and interpreted most of the C-MABQv2 statements and responded as intended suggesting good face validity. The presentation, layout, font size, colour and style were well received, with no change recommended. During cognitive interviews, patients recommended very minimal changes to the C-MABQv2 as shown in supplementary file IV. When there were two different statements for the same determinants, patient preferred statements were kept for final version C-MABQ.

Statements 31 and 32 represented the same concepts but were checked with patients for their preferred statement. Four patients preferred statement 31 over 32 and others did not have any preference, therefore we chose statement 31 for the final C-MABQ which now has a total of 50 statements – referred to as ‘C-MABQ’ from here onward. Two statements (5 and 15) initially phrased as ‘unsure’ were recommended to be changed to ‘don’t know’.

The final C-MABQ statements, their reordering as recommended by healthcare professionals and patients and their corresponding TDF domains are presented in table 1 below. For the full final C-MABQ with instructions, response options and scoring method see supplementary file V.

Section ONE Statements (TDF domains) With five response options: 1) Very Difficult 2) Difficult 3) Neither Easy nor Difficult 4) Easy 5)Very Easy
1. Remembering to take my medications is (Memory, attention and decision process)
2. Remembering to collect my medications from the doctors or pharmacy is (Memory, attention and decision process)
3. Sticking to medications taking routine is (Memory, attention and decision process)
4. Getting medications related advice from my mental health team is (Environmental context and resources)

Section TWO Statements With these five response options: 1) Strongly Disagree 2) Disagree 3) Neither Agree nor Disagree 4) Agree 5) Strongly Agree
5. I don't know how and when my healthcare professional would like me to take my medications. (Knowledge)
6. I don't understand why I am prescribed my medications. (Knowledge)
7. I don't recognise myself as someone with bipolar disorder. (Intentions)
8. I don't need medications for my mental health condition. (Intentions)
9. I don't want to take medications for my mental health condition. (Intentions)
10. I prefer to use treatments other than medications. (Intentions)
11. I believe that mental health medications are harmful. (Beliefs about consequences)
12. I have read or heard things that make me not want to take my medications. (Social influences)
13. I feel that my medications have been imposed upon me. (Social/professional role and identity)
14. I don't like the idea of my mood being controlled by medications. (Social/professional role and identity)
15. I don't know what would happen to my mental health if I stopped taking my medications. (Knowledge)
16. I don't want people to know that I have a mental health condition. (Social influences)
17. People around me do not like me to take my medications. (Social influences)
18. I feel that my mental health team listens to me. (Social influences)
19. My mental health team is there for me when I need them. (Social influences)
20. I have a good relationship with my mental health team. (Social influences)
21. My friends and family are supportive of my mental health. (Social influences)
22. People judge me because of my mental health condition. (Social influences)
23. I believe that I will become unwell if I stop taking my medications. (Beliefs about consequences)
24. I have a set routine to help me take my medications at the right time. (Memory, attention and decision process)
25. Taking my medications as prescribed is a top priority for me. (Goals)
26. In terms of my physical and mental health, the positive effects of my medications outweigh any negative effects. (Memory, attention and decision process)
27. I believe that taking my medications keeps me well. (Beliefs about consequences)
28. I have ways to help me remember to take my medications at the right time. (Memory, attention and decision process)

29. I need to continue to take my medications no matter what my mood is like. (Knowledge)
30. Getting unwell and being hospitalised because of my mental health condition really frightens me. (Emotion)
31. I worry that I may harm myself or others if I do not take my medications as prescribed. (Emotion)
32. Other things take priority over my medications. (Goals)
33. My medications make it difficult for me to get on with my life. (Goals)
34. I have practical problems with collecting my prescriptions or medications. (Environmental context and resources)
35. I worry about getting addicted to my medications. (Emotion)
36. I worry about the side effects of my medications. (Emotion)
37. I worry about being sectioned (detained under the Mental Health Act) if I do not take my medications as prescribed. (Emotion)
38. I fear of not being myself if I take my medications. (Emotion)
39. I am fed up with taking medications to control my mental health condition. (Emotion)

Section THREE Statements
With these five response options: 1) Totally Unacceptable 2) Unacceptable 3) Neutral
4) Acceptable 5) Perfectly Acceptable
40. The extent to which my medications are working to improve my mental health is (Environmental context and resources)
41. The side effects I'm getting from my medications are ((Environmental context and resources)
42. The amount of support that I am getting from my friends and family to take my medications is (Social influences)
43. In my culture, a mental health diagnosis is (Social influences)
44. In my culture, taking mental health medications is (Social influences)
45. How much I am involved in the decisions about my treatment is (Social/professional roles and identity)
46. The prescription cost for me is (Environmental context and resources)
47. The number of medications prescribed for my mental health condition is (Environmental context and resources)
48. The type of medications (For example: pills, injections) prescribed for me is (Environmental context and resources)
49. The doses (amounts) of the medications prescribed for me are (Environmental context and resources)
50. The number of times a day I have to take my medications is (Environmental context and resources)

Table 1: The Final C-MABQ.

The total number of words in each statement ranged from 6 to 20 words (median of 11 words and mean of 10.5 words). Forty C-MABQ statements (80%) had less than 15 words. The final 50-item C-MABQ had a Flesch-Kincaid reading ease test score of 66 indicating good readability that should be understood by 13 to 15 years old.

Discussion

This study outlines the rigorous development of C-MABQ; a 50-item, theory and evidence-informed adherence questionnaire designed to identify individuals' adherence determinants. Grounded in behaviour change theory, the C-MABQ was developed through a multi-phase process involving behavioural science experts, healthcare professionals review and cognitive interviews with patients, ensuring both theoretical robustness and practical relevance. The final C-MABQ is concise yet comprehensive demonstrating both face and content validity. This development approach aligns with COSMIN (CONsensus-based Standards for the selection of health Measurement INSTRuments) guidance, which emphasises the importance of ensuring content validity through stakeholder involvement and iterative refinement [21]. This validation process ensured clarity and user accessibility of the C-MABQ with good readability score and a patient-centred design. Mapping each C-MABQ statement to a TDF domain further enhances its utility compared to existing adherence questionnaires.

Design and Structure

The C-MABQ was designed to optimise usability, clarity, and data quality through a five-point Likert scale applied across three logically structured sections. Each section aligns with the nature of the adherence determinant being assessed-for instance, questions about medication routines used the Easy/Difficult scale, while emotional and social issues aligned with Agree/Disagree, and determinants like formulation were matched to Acceptable/Unacceptable. This tailored approach ensures accurate and meaningful responses while minimising participant burden. The questionnaire begins with simple, broadly applicable items to ease respondents into the survey [9]. It then progresses logically, balancing relevance and ease to more emotionally nuanced topics towards the middle to maintain engagement, support smooth flow and reduced cognitive burden [22]. Prioritising patient needs and experiences throughout the development process contributed to the questionnaire's clarity, relatability, and accessibility. The use of natural, conversational language helped ensure that items were easy to understand, while thoughtful sequencing of sections supported participant engagement and minimised cognitive burden.

Review of questionnaires by experts is recommended as a part of testing face and content validity [10]. Thus, initial discussions with behavioural science experts and review by healthcare

professionals fulfil this recommendation. Although no formal calculations of the face and content validity were conducted, the responses from the healthcare professionals show the face and content validity of C-MABQ. Healthcare professionals suggested additional adherence determinants; however, these were not added to the C-MABQ. Some were already addressed in existing items with slightly different wording- for example, 'being able to talk to the healthcare team about side effects' is reflected in statement 4, and 'not liking the effects of their mood being artificially flattened or controlled' is captured in statement 14. Other suggestions, such as low mood or substance misuse, were considered non-modifiable [1] within the scope of this study and therefore excluded. The minimal changes required during cognitive interviews provide confidence in the robust development process of the C-MABQ items.

Readability and Accessibility

Emphasising readability and accessibility during development likely enhanced the C-MABQ's real-world applicability. The use of concise, clearly worded items aligns with established guidelines for health communication, supporting comprehension and reducing cognitive effort for respondents. The average item length was 11 words, with none exceeding 20, reflecting a conscious effort to minimize cognitive burden on respondents. This design choice is consistent with established readability standards [16-18] and enhances user engagement and understanding. Such considerations are particularly important in diverse populations where health literacy levels may vary.

Notably, the C-MABQ achieved a Flesch-Kincaid readability score of 66, surpassing the commonly cited threshold of 60 for health-related materials [20,23]. This level of readability is particularly significant given the well-documented challenges in developing patient-facing tools that are both comprehensive and accessible [20,23]. The score reflects C-MABQ's potential to be understood by individuals with a broad range of education levels, thereby enhancing its inclusivity and practical utility in diverse community contexts.

Comparison with other Adherence Questionnaires

While several validated tools exist to assess medication adherence in bipolar disorder - such as Beliefs about Medicines Questionnaire (BMQ), Brief Adherence Rating Scale (BARS), Brief Evaluation of Medication Influences and Beliefs (BEMIB), Medication Adherence Rating Scale (MARS) Medication Adherence Report Scale - 5 (MARS - 5) and Reported adherence to medication scale (RAM) [24]- these tools largely quantify adherence behaviours without fully exploring the multifaceted reasons behind non-adherence. While some (e.g., BMQ) capture some adherence determinants, they tend to be narrow and limited such as medication beliefs and forgetfulness. Our findings highlight the importance

of capturing a broader range of adherence determinants-including emotional, social, and intentional factors, many of which are underrepresented in existing tools. This aligns with the COSMIN guidance, which emphasises the importance of content validity as the most critical measurement property when developing patient-reported outcome measures [21]. Moreover, many existing tools lack a foundation in comprehensive behavioural science, which is critical for developing effective interventions. The C-MABQ addresses this gap by integrating the TDF [15], ensuring that the C-MABQ is not only theoretically grounded but also aligned with COSMIN's emphasis on relevance, comprehensiveness, and comprehensibility of items. Furthermore, each C-MABQ statement is mapped to a TDF domain which are linked with behaviour change techniques [25]. Thus, C-MABQ provides valuable actionable insights for clinicians to provide personalised adherence support to improve adherence and patient outcome.

Strengths and Limitations

A key strength of the C-MABQ development was the collaborative involvement of a multidisciplinary team and patients throughout the process. Active collaboration with both patients (who will complete it) and healthcare professionals (who will use the C-MABQ to support personalised adherence) ensured the tool is both clinically relevant and user-friendly. This inclusive development process enhanced the questionnaire's face and content validity, supporting its acceptability and future implementation in real-world settings. Second, the study demonstrated strong methodological rigour by adhering to best practice recommendations. The iterative refinement process allowed for thoughtful adjustments, such as refining terminology and response options to improve clarity and engagement. Third, the questionnaire's high readability is particularly noteworthy. This is especially important in mental health contexts, where cognitive load and literacy challenges can affect engagement with written materials. Finally, the mapping of C-MABQ items to the TDF is a unique contribution in the field of mental health medication adherence, enhancing the tool's theoretical grounding and practical utility.

Despite its strengths, the study has some limitations. The C-MABQ statements were developed based on the most relevant adherence determinants identified and prioritised in our previous studies [1,11]. While this focused approach may not capture every possible adherence determinant, this prioritisation was informed by patients and their families [11] ensuring C-MABQ remains concise, relevant and engaging for respondents. Calculation of face or content validity index to evaluate face and content validity instead of subjective evaluation would have added robustness to the study. However, the discussion with behavioural science experts, review by healthcare professionals and cognitive interviews with patients aimed to refine the C-MABQ, and thus subjective

assessment was deemed sufficient. Additionally, specific questions were used during review by healthcare professionals and cognitive interviews, which added the scientific rigour required to fulfil the aim of the study.

Implications for Practice and Research

The C-MABQ has significant potential to improve clinical practice by enabling personalised adherence support. By identifying individual-level barriers and facilitators, clinicians can tailor interventions more effectively. This may include pharmacological, emotional, social, or practical support-such as addressing specific information needs, providing counselling on risks and benefits, or using motivational interviewing as needed. It also facilitates structured conversations about adherence, supporting shared decision-making and enhancing therapeutic relationships; critical determinants of adherence [11].

In research, the C-MABQ can provide a valuable framework for identifying an individual's adherence determinants. It can also be used as a foundation for development of personalised adherence support and implementation research. Psychometric evaluation and validation of the C-MABQ, including assessments of reliability, construct validity and criterion validity is already completed (pending publication). Future research should focus on the linking C-MABQ items to behaviour change technique and test its feasibility in clinical practice. There is also potential to adapt the C-MABQ for digital platforms, enabling integration into electronic health records or mobile health applications. This could support real-time monitoring and intervention, enhancing the scalability and impact of C-MABQ.

Conclusion

The C-MABQ represents a significant advancement in identifying medication adherence determinants in BD. With its rigorous design, clarity, and accessibility, it empowers clinicians to identify individual's key adherence determinants-laying the foundation for personalised adherence support to improve patient outcomes.

Consent for publication

All authors have reviewed and consented for publication.

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Availability of data and materials

Most data and materials are provided as supplementary file.

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