Development of the My Medicines and Me (M3Q) side effect questionnaire for mental health patients: a qualitative study

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Abstract

Objective: The objective of this study was to assess the acceptability, content validity and usability of the My Medicines and Me (M3Q) self-report side effect questionnaire.

Methods: Eight focus groups consisting of mental health patients, carers, general practitioners, psychiatrists, mental health nurses and pharmacists were conducted, involving 78 participants. Two researchers independently examined the transcriptions and analysed the data thematically using an inductive method.

Results: The findings supported changes to the formatting, length and phrasing of questions in the original version of the questionnaire. Although the groups provided differing views on the usability of the M3Q in clinical practice, the patient and carer groups were unconditionally in favour of such a tool to be used systematically to describe patients' subjective experiences with side effects.

Conclusion: The differing contribution made by all groups involved in the administration and completion of the M3Q assisted with content validity of the questionnaire. The acceptability and usability of this novel side effect questionnaire was also explored, with many participants agreeing it was a necessary tool for a patient centred approach to treatment. Following implementation of the changes to the current format of the questionnaire, investigation into the uptake and use in clinical practice should be carried out.

Keywords: adverse effect, psychotropic medication, subjective experience, tool

Background

In the past two decades we have seen many advances in the pharmacological treatments available for mental health patients. At the same time we have also witnessed the move towards shared decision making, with patients becoming increasingly involved in decisions concerning their treatment and recovery [Dassori *et al.* 2003; Mahone, 2008; Slade, 2012].

Despite these advances, the unavoidable issue of psychotropic medication side effects, some of which can be intolerable, still remains unresolved. Side effects are reported as the main reason for nonadherence to pharmacological treatment, patients' negative attitudes towards medication and reduced quality of life of patients under treatment [Dassori

et al. 2003; Staring *et al.* 2009]. Nonadherence has serious consequences in mental health patients including relapse and rehospitalization, relationship breakdown, loss of housing, loss of employment, involvement in substance abuse, crime and suicide [Ascher-Svanum *et al.* 2008; Yen *et al.* 2009; Chapman and Horne, 2013]. Many earlier studies have shown a link between subjective reporting of side effects and adherence [Van Putten *et al.* 1981; Hogan *et al.* 1983; Naber *et al.* 1994] and that patients will often only report side effects if directly asked [Weiden and Miller, 2001; Yusufi *et al.* 2007]. For this reason, there is a need for a simple patient centred tool that measures the most bothersome patient perceived medication side effects that may eventually lead to discontinuation of treatment.

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A recent literature review identified six self-report questionnaires (SRQs) that assess subjective experiences of medication side effects from the mental health patients' point of view [Ashoorian *et al.* 2014]. This review further identified a need for a side effect questionnaire that should:

- (i) be applicable to all psychotropic medications,
- (ii) be concise so that it can be filled out prior to the patient's every visit with the clinician
- (iii) allow patients to identify the most bothersome side effects and be given the opportunity to elaborate on the impact these effects are having on their quality of life through open-ended questions.

In 2010, our group at The University of Western Australia developed a side effect questionnaire, the Enhancing Quality Use of Medication Self Report Questionnaire (EQUIM-SRQ), to address this gap and to explore the impact of psychotropic medication side effects on patients' quality of life. This SRQ was piloted across two mental health outpatient clinics with 29 participants [Ashoorian *et al.* 2012]. The results of this study made it evident that future work needed to be carried out to refine and validate the SRQ in order to carry out further research in a larger sample and introduce its use into practice. The EQUIM-SRQ, renamed the My Medicines and Me Questionnaire (M3Q) for this study, is a questionnaire for identifying medication side effects that mental health patients are experiencing and their perceptions of these effects. It consists of five sections utilizing a combination of closed questions (checklist) and open questions.

The aim of this study was to assess the acceptability, content validity and usability of the M3Q.

Methods

Design

The University of Western Australia's Human Research Ethics Committee (HREC) granted ethics approval for the study. This qualitative study used focus groups to generate data as they enable a group of participants to share their views, thought and experiences [Krueger and Casey, 2000; Bajramovic *et al.* 2004]. The focus groups were designed to provide 'supplementary data' to refine the formatting, length and phrasing of questions in

the validation and development of the M3Q [Streiner and Norman, 2008; Liamputtong, 2013]. Eight focus groups were held with key stakeholders between July and September 2012. All group discussions were audio taped with the permission of the participants. Two recorders were used so that a backup was available in the event that one malfunctioned. Two research members were present at each group. One member, an expert in conducting focus groups facilitated the group; the other took detailed handwritten notes. All groups were led by the same facilitator to minimize variation in the questioning style. All study authors contributed to the development of the open questions, which were used by the facilitator to guide the group discussions (Figure 1). Focus groups were conducted until saturation, or theme repetition, was reached [Liamputtong, 2013]. At the conclusion of the discussion, the participants were asked to write their own personal summary of the most important issues, including any changes they would make to the current format of the questionnaire.

Study sample and recruitment

We used a combination of purposeful and convenience sampling that resulted in a total of 78 participants who were reflective of a range of experiences, knowledge and demographics [Creswell, 2007]. The eight focus groups comprised the following:

1. Carers of mental health patients
2. Mental health patients
3. Psychiatrists practicing at a public psychiatric hospital and community practice
4. Psychiatrists (and psychiatrists in training) at a mental health ward of a public hospital
5. General practitioners (GP) at a private practice
6. Mental health nurses at a public hospital
7. Pharmacists practicing at a public psychiatric hospital
8. Pharmacists practicing in community and academia

We purposively selected psychiatrists and pharmacists (two groups each) from a range of backgrounds to gain insight from participants with varied work experiences. The similarities within each group based on their backgrounds capitalized on the participants' shared experiences and increased the quality of the data [Kitzinger, 1995]. The patients were recruited *via* a newsletter published by the Mental Health Commission of

What do you think would be the benefits of using this questionnaire?	<ul style="list-style-type: none"> • To the patient? • To the clinician?
OR	
What do you value about this questionnaire?	Do you see this as clinically significant? Would you use this in your practice?
Do you think the questionnaire is 'user-friendly'?	<ul style="list-style-type: none"> • Readability • Structure • Length • Visual layout • Colour scheme • Page sizes
What concerns do you have with the use of this questionnaire in practice?	
What would be the best way to administer the questionnaire?	<ul style="list-style-type: none"> • At the clinician's office • At the GP practice • At the pharmacy • Online • iPhone application
What degree of assistance should be offered to fill out the questionnaire?	<ul style="list-style-type: none"> • Self-report • Semi-structured interview

Figure 1. Open questions used in the focus groups.
GP, general practitioner.

Western Australian providing information concerning the study. The carers were recruited through ARAFMI (a community sector group for carers). All other participants were recruited through their places of employment and professional organizations.

Due to the nature of mental illness and specific requirements from HREC, the following inclusion criteria were set for the patient group: over 18 years of age; taking one or more psychotropic medication; possess basic English proficiency; ability and willingness to provide informed consent; self-managing without a carer; and currently not in acute phase of mental illness.

All participants were:

- provided with a written overview of the study (including the purpose);
- asked to provide informed consent (including consent to publish de-identified data collected from the discussions);
- assured that attendance was voluntary and withdrawal could occur at any time without prejudice; and
- asked to complete a demographics sheet.

A retail voucher was provided to the mental health patients and carers who attended the focus groups as a nominal compensation for their time and travel. All other participants attended their respective focus groups during ordinary work hours and therefore were not provided with a voucher.

Data analysis

All focus group discussions were transcribed verbatim. Two researchers independently examined the transcriptions and analysed the data thematically using an inductive method [Thomas, 2006]. Rigorous reading and coding of the transcripts allowed major themes to emerge. Similarities and differences across the groups were examined and compared around the key questions and new emerging themes were also noted. The researchers then compared their individual findings and sought convergence when there was disagreement to reach consensus [Creswell, 2007].

Results

A total of 10 patients, 8 carers, 28 physicians, 10 nurses and 22 pharmacists participated in a total of

Table 1. Demographic characteristics of participants.

Group	Age range	Mean age	Male	Female
1. Carers	53-80	69	5	3
2. Mental health patients	28-70	51	2	8
3. Psychiatrists	27-59	41	7	7
4. Psychiatrists and Psychiatrists in training	21-50	29	5	4
5. GPs	43-49	46	3	2
6. Mental Health Nurses	24-52	37	4	6
7. Pharmacists Hospital	22-56	40	3	10
8. Pharmacists (community and academia)	28-67	43	2	7

8 focus groups. The demographic characteristics of the participants are presented in Table 1. Additional demographic information collected for the patient group included 'diagnosis'; this was to ensure a broad range of patient perspectives would be represented. The diagnoses of patient participants included depression, anxiety disorders, post-traumatic stress disorder, obsessive compulsive disorder, bipolar affective disorder, anorexia nervosa, schizophrenia and mixed personality disorder. It was found that 9 out of 10 patients had more than one diagnosis.

Six major themes and subthemes emerged in this study. These are listed in Table 2 and described below. Under each theme, findings from these various groups are presented. In this report, where all four healthcare professional groups (psychiatrists, GPs, pharmacists and nurses) agreed they are referred to collectively as 'HCP' (healthcare professional). Otherwise they are mentioned by their specific groups.

Benefits of the M3Q

HCPs liked the formality and standardized approach to talking about side effects through the use of an SRQ.

'If used regularly it can track changes over time'.
[psychiatrist 2, group 4]

Most participants liked the novelty of being able to rank side effects by the level of severity and impact on quality of life. In fact a number of patients and HCPs felt that what the HCPs might feel is a bothersome side effect is usually not the patients' perspective.

A psychiatrist commented:

Table 2. Six main themes derived (including subthemes).

1. Benefits of the M3Q
Ability to rank side effects
Empowerment of patients
Identification of embarrassing side effects
2. Disadvantages of the M3Q
Suitability for severely ill patients
Attribution of symptoms to medications
3. Logistics of administering and completing the M3Q
Frequency
Where and who to administer
4. Changes to the design and formatting of the M3Q
5. Additions to the M3Q
6. Implications of the M3Q for clinical practice

'I like how you ask them to identify what they personally feel are important issues for them ... and they rank ... that in terms of what they feel is important ... cause something might not ... really impede on their quality of life whereas another area ... it might actually affect them quite significantly'. [psychiatrist 8, group 4]

Similarly a patient commented:

'So they might be uncomfortable with anxiety or suicidal thoughts or whatever, but you're actually more concerned about the fact that you're putting on weight or not interested in sex or you've got restless legs. But you never get asked'. [patient 1, group 2]

A mental health nurse reflected:

'I think sometimes as nurses we concentrate on extrapyramidal side effects and weight gain when actually they weren't the most reported when we piloted LUNSERS (a side effect questionnaire) ...' [nurse 10, group 6]

A pharmacist commented:

'So I think that will give us a good idea of ... what side effects warrant a change in medication compared to, they might have a tremor or something that doesn't bother them then, you know, they don't mind staying on the medication, rather the psychiatrist or we saw the tremor we might consider changing them'. [pharmacist 9, group 7]

Many participants thought by just asking patients about their experiences could be validating and in some ways therapeutic.

'...helps articulate what we're experiencing'. [patient 4, group 2]

'I think is valuable because your experience is totally different to mine'. [carer 7, group 1]

'... they will feel valued, they will feel like you're taking them seriously'. [nurse 1, group 6]

'It sort of validates their feelings and I think it's a good outlet for them which we sometimes forget to ask'. [GP 4, group 5]

The word 'empowerment' came up several times in the patient and carer groups. They discussed how it helped them to articulate how they are feeling through the expression of their experience with medications. Participants of many groups thought that the questionnaire gave patients 'a voice'.

One patient commented:

'I've been on some really really strong psychotropic medications for 15 years and no one has ever asked me whether I've ever considered stopping my medication because of one of the effects. And then you stop your medication and they get shitty with you. So one of the benefits is just being asked'. [patient 1, group 2]

And she further commented:

'... so empowering for us as the consumer ... we get to choose ... most importantly what is most distressing to you and what is potentially going to stop you from taking your medication'. [patient 1, group 2]

The following are comments from the pharmacist groups:

'It's all about the clinicians imposing their will on patients and for us to go back to their perspective on how

they feel or what they feel about their care, in terms of medication, will also give them that sense of empowerment'. [pharmacist 11, group 7]

'... particularly if there's some expectation that someone is going to look at it and then possibly do something about it is very empowering for patients and carers which I don't think those sort of channels exist currently'. [pharmacist 6, group 8]

The participants in nearly all groups thought that the M3Q could be used as a tool to guide conversation; in particular it could help identify the more embarrassing side effects that patients would be uncomfortable to mention to their treating doctors.

The pharmacists pointed out that the M3Q could be a useful tool for accredited pharmacists conducting Home Medicines Reviews (HMR) [Australian Government Department of Health and Pharmacy Guild of Australia, 2013]. Several HCPs commented on the ability of this questionnaire to assist clinicians to work in partnership with their patients.

When GPs discussed the issue of nonadherence to medication it was acknowledged that:

'... I guess if there was a way of understanding what their perception was, that it could be part of us actually preventing that'. [GP 5, group 5]

Pharmacists commented on the impact of an SRQ in poly pharmacy:

'... can be used for the clinicians as well, because you know they tend to add lots of meds and not understand that they don't understand but they don't think about the impact that it has on patients so when they read the responses, then it will actually prompt them to rationalize things and think twice about what they add onto patient's profile because it's good for us to put multiple drugs to address issues but ... we don't think about just how the patient feels and affects them'. [pharmacist 11, group 7]

Patients also commented on this aspect:

'... when you're not well and you go to your GP the first thing he's going to do is: increase your medication. When you're given a form like this at least you can express and hope to God that he will take it in'. [patient 3, group 2]

Another patient pleaded:

'... health professionals need to take this seriously, this is my life, this is presenting my life to you, this is what I'm experiencing, you are the expert, help me to recover, because we are heading towards recovery. Because I find that even the health professionals stigmatize mental health'. [patient 10, group 2]

Disadvantages of the M3Q

The 18 patients and carers who participated in two separate focus groups were not able to identify a single disadvantage.

HCPs identified some issues. A recurrent theme with HCPs was that the M3Q would not be suitable for acutely ill patients and should only be administered to patients who have been stabilized. Another recurrent theme was that patients may mistakenly attribute symptoms they have to their medications, adding that *'some patients will tick everything or whatever they like'*. One psychiatrist added that this could actually work to the clinician's advantage:

'When you have somebody with a somatization disorder, they'll tick almost every single one of these boxes, I think it could be useful diagnostically as well'. [psychiatrist 2, group 2]

Some HCPs commented that the M3Q could potentially lead to confusion between what is actually a side effect and what is a symptom of mental illness, *'attribution of symptoms to drugs'*. In the psychiatrist and GP groups there was discussion on whether there was an un-intended effect that the checklist of side effects could scare off patients and discourage them from taking their medications, especially patients suffering with paranoia, hypochondria or high anxiety.

'... they see that and think "gosh, if medication can cause all these side effects why should I be on it?"' [GP4, group 5]

'They'll read something then suddenly decide that they've got that and it must be due to their medication'. [nurse 9, group 6]

Logistics of administering and completing the M3Q

Frequency of completion. Most groups agreed that the questionnaire should be administered on

a regular basis, either monthly or every 3 months, as this would provide a measure of comparison for the treating healthcare professionals. It was also suggested that certain side effects such as weight gain and sexual dysfunction take longer to develop and therefore the need for continual monitoring.

Where and who to administer. Various avenues of administration were suggested in the focus groups, including pharmacists administering the M3Q at the time of dispensing repeat prescriptions of psychotropic drugs. Alternatively pharmacists could administer it during MedsCheck appointments [Pharmacy Guild of Australia, 2014] and feedback the information to the treating doctor.

'... community pharmacy could be an avenue for something like this, now that we're doing MedsChecks and longer consultations and scheduled consultations and remuneration. It would fit in nicely with a community pharmacist as focusing on medication and then providing a report to the doctor...to then address these issues clinically'. [pharmacist 1, group 8]

Caseworkers and mental health nurses were also suggested as being in a position to administer the questionnaire. During the GP focus group, it was discussed that the M3Q would best be addressed in psychiatric practice where consultations are longer; the limited 10–15 minute standard GP consultations in Australia are not conducive to administration and discussion of a side effect SRQ. However if there is a resident practice nurse, the questionnaire could be administered by the nurse at the GP practice.

As the M3Q is an SRQ, all groups agreed that patients should complete it themselves unless they are unwell. In those cases the patients suggested using a patient's advocate, someone the patient trusts to complete the questionnaire on their behalf. Individual patients and carers expressed their desire to have the questionnaire added to their e-record so that other healthcare professionals could have access to it.

Changes to the design and formatting of the M3Q

Several suggestions were offered to improve usability of the M3Q. Most groups wanted the font size increased and the length of the questionnaire reduced. A few participants in the HCP groups

suggested reducing the paper size from A4 to A5 for improved appearance and easier storage in patient files. Although the majority of groups thought the language level was appropriate for the average patient, the nurses suggested changing some of the terms to improve comprehension; for example, changing 'menstruation' to 'period' and 'adverse effects' to 'side effects'. Pharmacists suggested grouping the checklist items into categories such as 'sleep related issues', 'weight and appetite changes', etc.

Some participants in the GP and pharmacists groups thought the checklist of side effects should be eliminated as it could be leading, suggesting instead the patients should self-identify any effects they are experiencing. Other participants were in favour of the checklist adding that it was easier to tick the box for an embarrassing side effect such as sexual dysfunction instead of self-reporting those effects.

All HCP groups commented favourably on the question 'What benefits do you gain from taking your medication?' as it will provide an understanding of the patient's perspective of the medication's effectiveness.

All the groups liked the use of colours in the questionnaire and in addition, a number of psychiatrists suggested adding a picture that would symbolize the M3Q suggesting '*... an image could improve the uptake of the questionnaire*'. The checklist was retained as the benefits of including it outweighed the risks; however, all of the other changes suggested in this section were implemented.

Additions to the M3Q

Participants in the carers, nurses and pharmacists groups suggested asking about illicit drug use, alcohol consumption and smoking in the questionnaire. Participants of the patients, nurses and pharmacist groups suggested adding the following effects to the checklist: '*thermal regulation, restless leg, sedation, muscle stiffness, difficulty in sitting still*'. As a result, the following were added to the M3Q checklist: 'Have you had restless legs?' and 'Have you felt tired during the day?'.

Other suggestions for additions to the M3Q included adding an 'other' box at the end of the checklist so the patients have the opportunity to self-report any experienced effects not listed. The following statement was added to the questionnaire

as a useful contingency measure: 'In the last 4 weeks have you experienced any side effects that have not been listed?'.

Implications of the M3Q for clinical practice

All HCP groups commented on the time this would involve and the practicality of its use in practice. In addition, there were several concerns from the HCPs about the report of physical effects that in fact do not relate to psychotropic drugs. In patients who are on multiple drugs, it was commented that it was '*difficult to know which side effect relates to which drug*'.

In contrast both the patient and carer groups thought the M3Q could be the solution to better collaboration between GPs, psychiatrists and pharmacists, commenting that they believe there is a lack of communication between these groups in the management of patients' medicines.

Discussion

In this study, many issues relating to reporting of side effects of mental health medications through the use of a SRQ were identified. In particular the usability and acceptability of the M3Q were explored with the groups. Two groups, the patients and carers, unanimously expressed unconditional support for the idea of a side effect SRQ being completed prior to visits with their clinicians. Many of the psychiatrists and GPs were supportive of the idea, although concerns were raised about the lack of time in the current system to address the issues that would be raised. In addition, many HCPs had concerns about whether the questionnaire would be leading. The nurses provided very practical ideas for the wording, formatting and administration of the questionnaire in practice. The pharmacists were also of the view that a self-report questionnaire could be very useful in gaining knowledge of how the patient is managing their current medications and could provide a platform for communication between the pharmacist, patient and treating physician.

Participant perceptions that the SRQ would aid communication are supported by the literature. Clinicians and other healthcare professionals often do not see the overall effect of medications on the daily life of their patients and may not be fully aware of the impact of side effect on the patient, particularly if the patient does not tell them [Fakhoury *et al.* 2001; Happell *et al.* 2004; Pope

and Scott, 2003]. These perceived side effects and resulting distress levels have long been associated with increased rates of nonadherence [Dassori *et al.* 2003; Day *et al.* 1998; DiBonaventura *et al.* 2012; Yen *et al.* 2009].

There is also empirical support for the recommendation that the SRQ be administered regularly. Distress levels associated with side effects are dynamic and what was an acceptable side effect to a patient in the past may not be acceptable today as the nature, severity and tolerance to those effects may change over time [Weiden and Miller, 2001]. Therefore, there needs to be an effective communication system in place to continually assess and distinguish between the appearance of specific side effects and the fluctuation in the degrees of distress they produce [Dassori *et al.* 2003]. Interestingly, there seems to be considerable discrepancy between patients and clinicians perception of the impact of specific side effects [Day *et al.* 1998; Farcas *et al.* 2010; Gerlach and Larsen, 1999; Naber, 2008]. Self-report questionnaires are one of the most effective ways to capture patient perceptions on possible side effects (and resulting distress levels) and may be helpful in allowing open communication between patient and clinician, thus improving adherence and premature discontinuation of psychotropic medications [Foster *et al.* 2008].

Healthcare providers are continually striving towards a system that is geared towards patient centred care and healthcare professionals' alliance in the delivery of that care. The patients and carers in this study supported the use of a side effect questionnaire that can capture their subjective experiences with medications. Although some HCPs might consider an SRQ time consuming, in the long run helping patients identify and manage the side effects of psychotropic medications can lead to positive treatment outcomes and strengthening of the patient/clinician relationship. It is also important to keep in mind that the M3Q is a communication tool, not a diagnostic tool. Patients may check items that are not clinically relevant or might not necessarily represent specific known medication side effects; however, they can serve to alert clinicians to issues that require further attention and discussion. In this study many HCP participants agreed the M3Q would be a simple means of providing the platform required to improve communication between service providers and patients, thus supporting its acceptability and usability in clinical practice.

Strengths and limitations

The main strength of this study was the ability to recruit such a large number of participants from such varied backgrounds. By inviting input from the various stakeholders, the researchers were able to establish credibility with the local community with regard to the purpose of future research in this area. Focus groups can be helpful in ongoing research efforts with populations that are vulnerable [O'Brien, 1993] such as mental health patients, as they demonstrate to members of that population that the researchers are actually interested in listening to what they have to say.

An even number of patient and HCP groups would have been ideal and therefore the inclusion of only one patient group was considered a limitation of this study. In addition, it should be noted that patients and HCPs in countries other than Australia with different healthcare systems might have different experiences to those expressed by the participants in this study.

Other limitations were those common to focus group methodology: that qualitative data cannot be generalized; that the data could have been misinterpreted; and that the facilitator could have lead participant comments [Ruff *et al.* 2005]. In our study we compensated for these by having two independent reviewers analyse the data. In addition, the questions asked by the facilitator were open questions designed to generate discussion without manipulating the direction of the conversations.

Future research

Formal psychometric testing has been carried out on the closed questions resulting in 32 items in the checklist component [Ashoorian *et al.* 2015]. The final version of the M3Q is given in Appendix 1. Investigation into the uptake and use of the questionnaire in clinical practice should be carried out. Initially the tool will be trialled in community mental health clinics where psychiatrists have extended appointments with patients, thus allowing sufficient time for a meaningful dialogue around the experience of taking psychotropic medications. Other clinical settings for implementation of the tool will include GP practices where mental health patients can attend an extended appointment for 'chronic disease management' with practice nurses. Community and hospital pharmacists are also in a prime position to use the M3Q as a means to begin a dialogue around experiences and adherence issues relating to psychotropic medications. In particular,

HMRs and MedsCheck services provide the opportunity for formalized appointments with funding provided to pharmacists under the Medicines Use Review Program (Fifth Community Pharmacy Agreement) [Australian Government Department of Health and Pharmacy Guild of Australia, 2015]. These services include a review of a patient's medications with the aim of identifying any problems a patient may be experiencing and improve the effective use of medicines.

Although this questionnaire is primarily designed for use by mental health patients, many participants discussed future development of a version of this questionnaire for carers as they might have different perspectives on the nature and impact of experienced side effects in patients. An online electronic version of the M3Q was also recommended to maximize uptake.

Conclusion

The findings of this study provided a valuable contribution to knowledge surrounding the acceptability, content validity and refinement of the test questionnaire, the M3Q. In particular, the differing contribution made by all groups that would potentially be involved in the administration and completion of the M3Q was invaluable in assessing content validity. The focussed attention on the refinement of the previous version of the M3Q has resulted in significant changes to the formatting, design and wording of items in the questionnaire.

There is a need, as expressed by patients and their carers, in everyday clinical practice for use of a tool like the M3Q to allow the patients to express their subjective beliefs about their medications, thus informing clinicians about the most bothersome side effects and the impact of the effects on their lives. This is significant as inability of the patient to provide this information and of clinicians to effectively probe for this information could lead to these side effects being undetected and untreated, often for extended periods of time. A simple tool like the M3Q could make a significant contribution to the collaborative discussions between patients and healthcare professionals thus supporting the notion of a multidisciplinary 'patient centred care'.

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Conflict of interest statement

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Appendix 1.

THE UNIVERSITY OF
WESTERN AUSTRALIA

My Medicines & Me Questionnaire (M3Q)

A side effect questionnaire for mental health medications

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LIST ANY MEDICATIONS YOU ARE CURRENTLY TAKING:
(Include all prescription, over-the-counter medications and natural therapies)

Drug:

Dose:

Consumer name: _____

Clinic attended: _____

To be completed in the clinic.

Reviewed by: _____

Comments:

Side effects

Mental health consumers can experience many benefits from their prescribed medications. However, they can also experience adverse side effects. Please go through this list and only tick the boxes if you have experienced the following side effect to any degree **IN THE PAST 4 WEEKS**.

General health

- Have you felt weak? ☐
- Have you felt drugged or like a zombie? ☐
- Have you been sweating more than usual? ☐

Sleep related issues

- Have you felt tired during the day? ☐
- Have you had difficulty staying awake during the day? ☐
- Have you had difficulties waking up fresh in the morning? ☐

Weight and appetite changes

- Have you gained weight? ☐
- Do you think some foods taste different/odd? ☐
- Have you felt more hungry than usual? ☐
- Have you been more thirsty than usual? ☐

Bowel and bladder habits

- Have your stools been hard or difficult to pass? ☐
- Have you needed to go to the toilet often? ☐

Skin changes

- Has your skin been more sensitive to the sun? ☐
- Have you noticed any areas of darker skin? ☐

Diabetes

- Do you have diabetes? ☐
- Have you been told that your blood sugar levels are high? ☐
- Have you noticed a change in your blood sugar levels? ☐

Visual problems

- Has your vision been blurry? ☐
- Have your eyes felt dry and gritty? ☐

Oral problems

- Have you found that your words don't come out clearly? ☐
- Have you found it difficult to swallow? ☐

Mood

- Have you felt anxious? ☐
- Have you felt agitated? ☐
- Have you felt sad? ☐
- Have you lost interest in enjoyable things? ☐

Uncontrollable face and body movements

- Have you experienced fits/jerks? ☐
- Have your arms or legs been shaky? ☐
- Have you had restless legs? ☐

Sexual health

- Have you been less interested in sex? ☐
- Have you found it difficult to enjoy sex? ☐
- Have you been unable to reach orgasm? ☐
- Have the areas around your nipple been sore and/or swollen? ☐

In the last 4 weeks, have you experienced any side effects that have not been listed?

FROM THE SIDE EFFECTS YOU HAVE IDENTIFIED ABOVE PLEASE RANK UP TO 3 THAT ARE YOUR MOST BOTHERSOME

[1 being the most bothersome and 3 being the least bothersome]

#1

#2

#3

SIDE EFFECT SPECIFIC QUESTIONS

Please elaborate on the three most bothersome side effects you listed on the previous page.

Side Effect #1

1. How often do you experience this side effect?

☐ Daily _____ ☐ Weekly _____ ☐ Monthly _____

How long does it last?

2. Do you know what medication may be causing this side effect?

☐ No

☐ Yes → Which medication:

3. How does it impact your daily living?

(e.g. Prevents you from being in public places, going to work, participating in activities)

4. Do you think other people are aware of this side effect?

☐ No

☐ Yes → Please explain: (What do they do or say to make you feel this way?)

SIDE EFFECT SPECIFIC QUESTIONS

Side Effect #2

1. How often do you experience this side effect?

☐ Daily _____ ☐ Weekly _____ ☐ Monthly _____

How long does it last?

2. Do you know what medication may be causing this side effect?

☐ No

☐ Yes → Which medication:

3. How does it impact your daily living?

(e.g. Prevents you from being in public places, going to work, participating in activities)

4. Do you think other people are aware of this side effect?

☐ No

☐ Yes → Please explain: (What do they do or say to make you feel this way?)

SIDE EFFECT SPECIFIC QUESTIONS

Side Effect #3

1. How often do you experience this side effect?

☐ Daily _____ ☐ Weekly _____ ☐ Monthly _____

How long does it last?

2. Do you know what medication may be causing this side effect?

☐ No

☐ Yes → Which medication:

3. How does it impact your daily living?

(e.g. Prevents you from being in public places, going to work, participating in activities)

4. Do you think other people are aware of this side effect?

☐ No

☐ Yes → Please explain: (What do they do or say to make you feel this way?)

GENERAL QUESTIONS**1. Have you ever considered not taking your medication due to the severity of the side effects?**☐ No☐ Yes → How often? ☐ Often _____
☐ Sometimes _____

Which side effects in particular?

Have you ever actually stopped taking your medication?

☐ No☐ Yes → Why?

2. Medications have benefits. What benefits do you gain by taking your medication?

3. Is there anything else you would like to tell me regarding your medications?