



Atrial Fibrillation Health Literacy Questionnaire (AFHLQ): The development of an AF-specific health literacy questionnaire[☆]

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ABSTRACT

Background: Health literacy is a key enabler of effective behavioural modification in chronic diseases. While patient reported outcome measures (PROMs) exists for patient with atrial fibrillation (AF), none address risk factors comprehensively. The aim of the study was to develop and qualitatively validate a disease specific PROM that incorporates knowledge on risk factors and assesses interactive and critical health literacy of people living with AF.

Methods: The 47-item Atrial Fibrillation Health Literacy Questionnaire (AFHLQ) was developed and validated through a qualitative research design. Expert and Consumer focus groups, each consisting of seven participants provided opinion.

Results: The 47-item questionnaire consists of 5 domains: (1) what is AF, (2) what are the symptoms of AF, (3) why do people get AF, (4) management of AF, and (5) what measures can slow or prevent the progression of AF. Recommendations resulted in several changes to the original 47 item list during the qualitative validation process: 13 original items were removed, and 13 new items were added. The response categories were also simplified from a Likert scale to “yes”, “no” or “don’t know”.

Conclusion: A 47-item AFHLQ instrument was developed and validated with modifications made through clinical expert and consumer opinion. This tool has a potential to be used to evaluate and guide interventions at a clinical and population level to understand and improve AF health literacy and outcomes.

1. Introduction

Atrial Fibrillation (AF) is the most common sustained arrhythmia. It is associated with a five-fold increased risk of stroke [1], two-fold increased risk of heart failure [2], 1.4 fold increased risk of dementia [3] and two-fold increased risk of mortality [4]. The prevalence of AF is estimated at 2–4% in the general population, with 33.5 million patients globally, and further expected to increase 2.5-fold by 2050 [2]. Obesity, obstructive sleep apnoea, excessive alcohol consumption, hypertension, diabetes mellitus, physical inactivity, and congestive heart failure are well described risk factors for AF. The contemporary treatment of AF is

complex and not only consists of oral anticoagulation, rate and rhythm control but also risk factor management, emphasizing the need for innovative approaches such as integrated care model [5–7].

In recent years, health literacy has gained considerable global attention as an important contributor in preventing and managing chronic diseases associated with multiple modifiable behavioural risk factors [8]. Health literacy has been conceptualised as ‘the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate decisions’ [9]. People with chronic conditions report more difficulties than the general population in understanding health information and actively

Abbreviations: AF, Atrial Fibrillation; AFHLQ, Atrial Fibrillation Health Literacy Questionnaire; PROMs, Patient Reported Outcome Measures.

[☆] All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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engaging with healthcare providers [10]. Inadequate health literacy results in poorer quality of life, higher anxiety levels, increased hospital admissions and higher mortality rates [11,12]. A recent systematic review reported that health literacy interventions can improve health literacy in adults leading to changes in health behaviour and health

outcomes [13]. Although generic patient reported outcome measures (PROMs) have been utilised to assess health literacy, there is lack of a disease specific cardiovascular PROMs for patients living with AF.

An international survey has revealed that one in four patients with AF are unable to explain their cardiac condition and a third of the

Table 1
Modification of questionnaire items.

	Original Item V1.0	Original Item V2.0	Phase 1 (expert opinion) Modifications	Phase 2 (consumer opinion) Modifications
Response categories	Yes, No, Unsure	strongly agree, agree, neither agree or disagree, disagree, strongly disagree	strongly agree, agree, neither agree or disagree, disagree, strongly disagree	yes, no, don't know
Domain 1	What is AF?	What is Atrial Fibrillation?	What is Atrial Fibrillation (AF)?	What is Atrial Fibrillation (AF)?
Item 1	AF is an electrical heart problem that may cause a fast and irregular heartbeat	Atrial Fibrillation is an electrical heart problem that may cause a fast and irregular heartbeat	AF is an electrical heart problem that may cause a fast and irregular heartbeat	AF is an electrical heart problem that may cause a fast and irregular heartbeat
Item 2	AF is narrowing of the arteries that supply the blood to the heart, leading to heart attacks	Atrial Fibrillation is narrowing of the arteries that supply the blood to the heart, leading to heart attacks	AF is narrowing of the arteries that supply the blood to the heart, leading to heart attacks	AF is a narrowing of the arteries that supply the blood to the heart, leading to heart attacks
Item 3	AF may cause a failure of the heart pumping, leading to shortness of breath	Atrial Fibrillation may cause a failure of the heart pumping, leading to shortness of breath	AF may cause a failure of the heart pumping, leading to shortness of breath	AF may cause a failure of the heart pumping, leading to shortness of breath
Item 4	AF is a common cause of stroke	Atrial Fibrillation is a risk factor for stroke	AF is a risk factor for stroke	AF is a risk factor of stroke
Item 5	AF usually progresses from on and off, to a permanent state	Atrial Fibrillation usually progresses from the occasional episode to a permanent state	AF usually progresses from the occasional episode to a permanent state	AF usually progresses from occasional episodes to a permanent state
Item 6	AF can be identified by regularly checking the pulse	Atrial Fibrillation can be identified by regularly checking the pulse	AF can be identified by regularly checking the pulse yourself, or with a smart watch or BP machine	AF can be monitored by regularly checking the pulse yourself, or with a smart watch or blood pressure machine
Item 7	AF may increase the risk of dementia	Atrial Fibrillation may increase the risk of dementia	AF may increase the risk of dementia	AF may increase the risk of dementia
	An AF patient should go to their doctor or emergency room each time they experience AF	<i>Item removed</i>		
Item 8	Normal life is possible despite having AF	Normal life is possible despite having atrial fibrillation	It is possible for patients with AF to undertake their normal, daily activities	It is usually possible for patients with AF to undertake their routine daily activities
Item 9		Patients with chronic atrial fibrillation cannot work full-time (<i>New item</i>)	Patients with chronic AF cannot work full-time	Patients with chronic AF cannot work full-time
Item 10			Progression of AF is preventable (<i>New item</i>)	Progression of AF can be prevented
Domain 2	What are the symptoms of AF?	What are the symptoms of Atrial Fibrillation?	What are the symptoms of Atrial Fibrillation (AF)?	What are the symptoms of Atrial Fibrillation (AF)?
Item 11	No symptoms	Atrial Fibrillation can be without symptoms	AF can be without symptoms	AF can be without symptoms
Item 12	Shortness of breath	Shortness of breath	Shortness of breath	Shortness of breath
Item 13	Palpitations	Palpitations	Palpitations	Awareness of an irregular heartbeat (flutters)
Item 14	Body aches	Body aches	Body aches	Irregular pulse (<i>Item switched</i>)
Item 15	Irregular pulse	Irregular pulse	Irregular pulse	Body aches (<i>Item switched</i>)
Item 16	Chest discomfort	Chest discomfort	Chest discomfort	Chest discomfort
Item 17	Tiredness	Tiredness	Tiredness	Tiredness
	Nose or mouth bleeding	<i>Item removed</i>		
Item 18	Black out/fainting	Black out/fainting	Black out/fainting	Black out/fainting

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Table 1 (continued)

Item 19			Dizziness (<i>New item</i>)	Dizziness
Domain 3	Why do people get AF?	Why do people get Atrial Fibrillation?	Why do people get Atrial Fibrillation (AF)?	Why do people get Atrial Fibrillation (AF)?
Item 20	Allergies	Allergies	Allergies	Allergies
Item 21	Drinking too much alcohol	Drinking too much alcohol	Drinking too much alcohol	Drinking too much alcohol
	Exercising regularly	Exercising regularly	Exercising regularly	<i>Item removed</i>
Item 22	Exposure to sudden loud noises	Exposure to sudden loud noises	Exposure to sudden loud noises	Exposure to sudden loud noises
Item 23	Stress or anxiety	Stress or anxiety	Stress or anxiety	Stress or anxiety
Item 24	Obstructive sleep apnoea	Obstructive sleep apnoea	Obstructive sleep apnoea	Obstructive sleep apnoea
	Too much work	<i>Item removed</i>		
Item 25		Too much coffee (<i>New item</i>)	Drinking too much coffee	Drinking too much coffee
Item 26	High blood pressure	High blood pressure	High blood pressure	High blood pressure
Item 27	Being overweight	Being overweight	Being overweight	Being overweight
Item 28	AF can be spread from other people	AF can be spread from other people	AF can be spread from other people	AF can be transmitted from other people
			Drinking too many energy drinks (<i>New item</i>)	<i>Item removed</i>
Domain 4	Management of AF.	Management of Atrial Fibrillation.	Management of Atrial Fibrillation (AF).	Management of Atrial Fibrillation (AF).
	AF treatment is always aimed to restore normal rhythm	Atrial Fibrillation treatment is always aimed to restore normal rhythm	AF treatment is always aimed to restore normal rhythm	<i>Item removed</i>
	Blood thinners reduce the risk of stroke	Blood thinners reduce the risk of stroke	<i>Item moved below and modified</i>	
Item 29			Aspirin reduces the risk of stroke associated with AF (<i>New item</i>)	Aspirin reduces the risk of stroke associated with AF
Item 30			Oral anticoagulants reduce the risk of stroke (<i>New item</i>)	Oral anticoagulants reduce the risk of stroke associated with AF
Item 31	Electric shocks to restore normal rhythm may harm the heart	Electric shocks to restore normal rhythm may harm the heart	Cardioversion (electric shocks) as part of AF treatment may harm the heart	Electric shocks (cardioversion) as part of AF treatment may harm the heart
	AF can be treated by catheter ablation	Atrial fibrillation can be treated by inserting a tube into the heart via the top of the leg (catheter ablation)	AF may be treated by a specialised procedure (catheter ablation)	<i>Item removed</i>
Item 32	I can stop my blood thinners when I have no symptoms	I can stop my blood thinners when I have no symptoms	Patients with AF can stop blood thinners when they have no symptoms	Patients with AF can stop oral anticoagulants when they have no symptoms
Item 33	The prescribed medication can be missed now and then	The prescribed medication can be missed now and then	The prescribed medication can be missed now and then	Prescription medication can be missed without increasing risk
Item 34			When a patient with AF has a symptomatic episode, they should immediately present to the emergency department (<i>New item</i>)	When a patient has an AF episode, they should always present to the emergency department
Item 35	Black stools are one of the serious bleeding complications related to blood thinners	Black stools are one of the serious bleeding complications related to blood thinners	Black stools are one of the serious bleeding complications related to blood thinners	Black coloured bowel motions (stools) are one of the serious bleeding complications related to oral anticoagulants
Item 36	When AF patients regularly have minor (self-resolving) nose bleeds or gum bleeds, they should contact their doctor or specialist, while continuing to take their blood thinners	When AF patients regularly have minor (self-resolving) nose bleeds or gum bleeds, they should contact their doctor or specialist, while continuing to take their blood thinners	Patients with AF who experience minor bleeds (such as nose bleeds or gum bleeds) should contact their medical practitioner but should not stop taking their anticoagulants	Patients with AF who experience minor bleeds (such as nose bleeds or gum bleeds) should not stop their oral anticoagulants and contact their doctor

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Table 1 (continued)

Item 37	When you seek treatment or buy medication, you need to tell your doctor/ pharmacist/ nurse/ dentist that you take blood thinners regularly	When you seek treatment or buy medication, you need to tell your doctor/ pharmacist/ nurse/ dentist that you take blood thinners regularly	When patients with AF seek treatment or buy medication, they should tell the medical practitioner that they take blood thinners regularly	When patients with AF are prescribed other medications, they should tell the health provider that they take oral anticoagulants
Item 38	Blood thinners need to be stopped prior to an elective surgery	Blood thinners need to be stopped prior to an elective surgery	Oral anticoagulants may need to be stopped prior to an elective surgery	Oral anticoagulants may need to be stopped prior to an elective surgery
Item 39	Any form of exercise is dangerous for patients with AF	Any form of exercise is dangerous for patients with AF	Any form of exercise is dangerous for patients with AF	Any form of exercise is dangerous for patients with AF
	Patients with chronic AF cannot work full-time	<i>Item removed</i>		
		A patient with atrial fibrillation should go to their doctor or emergency room each time (<i>New item</i>)	When a patient with AF has a symptomatic episode, if they are feeling okay, they should rest at home and follow their action plan	<i>Item removed</i>
Item 40			Treatment plans for patients with AF may vary significantly (for example, some patients may need pacemakers and others may need ablation) (<i>New item</i>)	Treatment plans for AF may vary. For example, some patients may need pacemakers or other specialised procedures (catheter ablation) in addition to medication
Domain 5	What measures can slow or prevent the progression of AF?	What measures can slow or prevent the progression of Atrial Fibrillation (AF)?	What measures can slow or prevent the progression of Atrial Fibrillation (AF)?	What measures can slow or prevent the progression of Atrial Fibrillation (AF)?
Item 41	Having your blood pressure controlled	Having your blood pressure controlled	Blood pressure control (where applicable)	Blood pressure control
Item 42	Giving up regular exercise	Regular exercise	Regular exercise	Regular exercise
	Staying away from other people who have AF	<i>Item removed</i>		
Item 43	Reducing alcohol intake	Reducing alcohol intake or abstaining from alcohol	Reducing alcohol intake or abstaining from alcohol	Reducing or stopping alcohol consumption
Item 44	Reducing weight is critical for people who are overweight	Reducing weight is critical for people who are overweight	Weight loss (where applicable)	Weight management
Item 45	Treatment of obstructive sleep apnoea if present	Treatment of obstructive sleep apnoea if present	Sleep apnoea management (where applicable)	Obstructive sleep apnoea management
	Progression of AF cannot be prevented	<i>Item removed</i>		
			Reducing energy drink intake (<i>New item</i>)	<i>Item removed</i>
Item 46			Diabetes management (where applicable) (<i>New item</i>)	Diabetes management
			Abstaining from coffee (<i>New item</i>)	<i>Item removed</i>
Item 47			Management of overactive thyroid disorders (where applicable) (<i>New item</i>)	Management of overactive thyroid

The highlighted cells indicate the changes, either new items or items removed.

patients are fearful of the disease [14]. Similarly, doctors reported AF difficult and time consuming to manage [14]. With a focus on better value in health care and focus on outcomes, the use of PROMs in being increasingly recommended in clinical practice [2,4]. Previous PROMs used in AF have primarily focused on knowledge related to warfarin treatment in patients with AF [15], symptoms or quality of life [16–18]. They neither assess the critical understanding of the disease nor the risk factors for AF which are an essential pillar of contemporary treatment of patients with AF [4,16–18]. Also, a mix of generic and AF-specific PROMs have been used to measure outcomes, they are yet to be utilised to guide clinical care [18]. Therefore, the aim of the current research was to develop and qualitatively validate a novel Atrial Fibrillation Health Literacy Questionnaire (AFHLQ) to assess the

knowledge and perception of AF in people living with the disease, with emphasis on risk factor management.

2. Methods

This was an evaluation study using qualitative research design to develop and validate an Atrial Fibrillation Health Literacy Questionnaire (AFHLQ) incorporating clinical knowledge, scientific literature, and expert and consumer opinion [19,20]. The study was considered an evaluation study with no risk to participants by the Central Adelaide Local Health Network Human Research Ethics Committee (CALHN-HREC), South Australia, and therefore was exempted from HREC approval. As per CALHN-HREC requirements, a final draft of the

Table 2
Atrial Fibrillation Health Literacy Questionnaire (AFHLQ).

What is Atrial Fibrillation (AF)	Yes	No	Don't Know
1 AF is an electrical heart problem that may cause a fast and irregular heartbeat	○	○	○
2 AF is a narrowing of the arteries that supply the blood to the heart, leading to heart attacks	○	○	○
3 AF may cause a failure of the heart pumping, leading to shortness of breath	○	○	○
4 AF is a risk factor of stroke	○	○	○
5 AF usually progresses from occasional episodes, to a permanent state	○	○	○
6 AF can be monitored by regularly checking the pulse yourself, or with a smart watch or blood pressure machine	○	○	○
7 AF may increase the risk of dementia	○	○	○
8 It is usually possible for patients with AF to undertake their routine daily activities	○	○	○
9 Patients with chronic AF cannot work full-time	○	○	○
10 Progression of AF can be prevented	○	○	○
Symptoms of Atrial Fibrillation (AF)?	Yes	No	Don't Know
11 AF can be without symptoms	○	○	○
12 Shortness of breath	○	○	○
13 Awareness of an irregular heartbeat (flutters)	○	○	○
14 Irregular pulse	○	○	○
15 Body aches	○	○	○
16 Chest discomfort	○	○	○
17 Tiredness	○	○	○
18 Black out/fainting	○	○	○
19 Dizziness	○	○	○
Why do people get Atrial Fibrillation (AF)?	Yes	No	Don't Know
20 Allergies	○	○	○
21 Drinking too much alcohol	○	○	○
22 Exposure to sudden loud noises	○	○	○
23 Stress or anxiety	○	○	○
24 Obstructive sleep apnoea	○	○	○
25 Drinking too much coffee	○	○	○
26 High blood pressure	○	○	○
27 Being overweight	○	○	○
28 AF can be transmitted from other people	○	○	○
Management of Atrial Fibrillation (AF)	Yes	No	Don't Know
29 Aspirin reduces the risk of stroke associated with AF	○	○	○
30 Oral anticoagulants reduce the risk of stroke associated with AF	○	○	○
31 Electric shocks (cardioversion) as part of AF treatment may harm the heart	○	○	○
32 Patients with AF can stop oral anticoagulants when they have no symptoms	○	○	○
33 Prescription medication for AF can be missed without increasing risk	○	○	○
34 When a patient has an AF episode, they should always present to the emergency department	○	○	○
35 Black coloured bowel motions (stools) are one of the serious bleeding complications related to oral anticoagulants	○	○	○
36 Patients with AF who experience minor bleeds (such as nosebleeds or gum bleeds) should not stop their oral anticoagulants and should contact their doctor	○	○	○
37 When patients with AF are prescribed other medications, they should tell the health provider that they take oral anticoagulants	○	○	○
38 Oral anticoagulants may need to be stopped prior to an elective surgery	○	○	○
39 Any form of exercise is dangerous for patients with AF	○	○	○
40 Treatment plans for AF may vary. For example, some patients may need pacemakers or other specialised procedures (catheter ablation) in addition to medications	○	○	○
What measures can slow or prevent the progression of Atrial Fibrillation (AF)?	Yes	No	Don't Know

Table 2 (continued)

What is Atrial Fibrillation (AF)	Yes	No	Don't Know
41 Blood pressure control	○	○	○
42 Regular exercise	○	○	○
43 Reducing or stopping alcohol consumption	○	○	○
44 Weight management	○	○	○
45 Obstructive sleep apnoea management	○	○	○
46 Diabetes management	○	○	○
47 Management of overactive thyroid	○	○	○

This survey aims to measure your current understanding of Atrial Fibrillation (AF). The answers will help your doctor to have the correct information to manage your AF.

There are three response categories: 'Yes' 'No' and 'Don't Know.'

- If you believe the statement is correct, please answer 'Yes'.
- If you believe the statement is incorrect, please answer 'No'.
- If you do not know if the statement is correct or incorrect, please answer 'Don't Know.'

manuscript was submitted to CALHN-HREC, and publication approval was granted. Informed written consent was obtained from experts and consumers participating in the focus groups.

2.1. Setting & participants

This study was conducted at Lyell McEwin Hospital, Northern Adelaide Local Health Network (NAHLN), South Australia. Participants were convenience sampled [21] for the two phases of expert and consumer focus groups based on their knowledge and experience with AF. The item list of the questionnaire was generated by the research team based on a formative model and then further developed through expert and consumer focus groups. A facilitator utilised a semi-structured interview schedule (Supplement 1) to promote group discussion in the focus groups. For phase one, medical (n = 4) and nursing experts (n = 2) in cardiology /cardiac electrophysiology and a general physician with interest in social determinants of health (n = 1) were invited to participate in an expert focus group (total n = 7) regarding the content validity and clinical and scientific merit of the AFHLQ. Similarly for phase two, consumers with lived experience of AF (n = 4), employees from the National Heart Foundation, South Australian branch (n = 2), and representative from community (n = 1) were invited to participate in a consumer focus group (total n = 7) to explore the consumer understanding, comprehension, and acceptability of the AFHLQ. The session duration for both groups was between one and two hours.

Questionnaire construct and target population [22]: In this study, the construct is health literacy about AF and the target population for testing is people diagnosed with AF.

Construction of an item list [22]: Through consensus among research team members, a 47-item questionnaire spanning different domains was developed to measure AF health literacy specifically among people diagnosed with this disease (Table 1, V1.0) and improvised with discussion (Table 1, V2.0). The AFHLQ was based on a formative model and the items and domains together formed the construct.

Qualitative analysis: The qualitative analysis of the questionnaire (Table 1, V2.0) was conducted through focus groups over two phases reflecting (1) expert and (2) consumer opinion. The analyses assessed psychometric properties such as content and face validity, acceptability, and perceived relevance. Phase one obtained expert opinion to investigate the clinical and scientific content and comprehensive nature of the item list and any discrepancies resolved by consensus. For example, investigating whether crucial information about AF from a patient perspective, such as common AF management strategies and misconceptions e.g., "aspirin reduces the risk of stroke associated with AF" addressing questionable efficacy of aspirin, and whether terms used in the item list, such as *anticoagulants* or *cardioversion* or *catheter ablation*, were clinically accurate. Phase two obtained consumer opinion to

inform the respondents' understanding of the items list. For instance, whether consumers with lived experience of AF understood what the items were measuring, if the language was readily compressible and unambiguous or whether the items list induced response burden (i.e., too long or too short).

Following the content analysis of the responses from each advisory group, the recommendations by experts/consumers were discussed amongst the research team [20]. The purpose of the research team discussions was to use the information gathered from each advisory group and analyse the data through content analysis to reach consensus on format, instructions, clarity, understandability, and relevance of the AFHLQ, informing items list refinement and modifications [23].

Atrial Fibrillation Health Literacy Questionnaire (AFHLQ): Forty-seven items were initially developed to measure AF health literacy across five domains (Table 1, Column 1, Original Item V1.0). The first domain evaluated knowledge about AF (section "What is AF?") and included items such as "AF is an electrical heart problem that may cause a fast and irregular heartbeat" or "AF is narrowing of the arteries that supply the blood to the heart, leading to heart attacks". The second domain evaluated knowledge about AF symptoms (section "What are the symptoms of AF?") and included items such as "No symptoms" or "Shortness of breath". The third domain evaluated knowledge about causes of AF (section "Why do people get AF?") and included items such as "Allergies" or "Drinking too much alcohol". The fourth domain evaluated knowledge about AF management (section "Management of AF") and included items such as "Atrial fibrillation treatment is always aimed to restore normal heart rhythm" or "Blood thinners reduce the risk of stroke". The fifth domain evaluated knowledge about preventive measures for AF (section "What measures can slow or prevent the progression of AF?") and included items such as "Having your blood pressure controlled" or "Giving up regular exercise". The original questionnaire (V1.0) had a 3-point response scale where patients would choose one of the following responses: "Yes", "No", "Unsure" which was changed to Likert scale (Table 1, Column 2, Original Item V2.0) after initial deliberation among research team.

2.2. Data collection

A neutral facilitator guided both advisory groups to ensure consistency across the data collection period using an advisory group interview schedule that included a 27-question semi-structured interview to evaluate *face validity* (e.g. "What do you think this item list is trying to measure?"), *content validity* (e.g. "Do you believe these items cover the necessary information about AF that patients need to know?"), *item clarity* (e.g. "Do you believe patients will understand all the items in the questionnaire?"), *questionnaire acceptability* (e.g. "Do you think patients might feel uncomfortable answering any of these questions?"), questionnaire length (e.g. "Is the questionnaire too long? Is the questionnaire too brief?"). The 27-question semi-structured interview questions were tailored for experts (e.g., "Do you believe patients will understand all the items in the questionnaire?") and patients (e.g., "Do you understand all the items in the questionnaire?"). The 27-question semi-structured interview is shown in Supplement 1.

To conduct the focus groups, recommended guidelines were adhered for sample size [24] and session length [25]. Any suggestions or concerns that were not comprehensively answered during the expert focus group and first research team discussion session were added to the second focus group interview guide to gauge consumer perspectives. The focus groups were conducted face to face, audio recorded, and transcribed verbatim.

2.3. Data analysis

The expert and consumer focus group transcripts were analysed by two investigators of the research team (GM, LC) in recommendations to ascertain the consensus reached during each of the advisory groups. To

limit the introduction of researcher bias on advisory group discussions, the analysts were not AF topic experts [26]. Any discrepancies between the two investigators were resolved by consensus with the help of a third investigator (MB). After completion of data analysis, corresponding changes were made to the AFHLQ. The suggested changes were discussed with each advisory group before instrument items were finalised. Where consensus was not unanimous within an advisory group, expert opinion was obtained within the research team discussion sessions to resolve outstanding items. Any suggested items resulting from the advisory groups, particularly the consumer advisory group, that were not supported by scientific evidence, were removed during the research team discussion sessions.

3. Results

The recommendations received from expert and consumer focus groups resulted in several changes to the item content and wording of the original 47 item pool (Table 1, Original Item V1.0). 13 original items were removed, and 13 new items added resulting in 47 items in the final version (Table 2). The original five domains ("What is Atrial Fibrillation (AF)?", "What are the symptoms of Atrial Fibrillation (AF)?", "Why do people get Atrial Fibrillation (AF)?", "Management of Atrial Fibrillation (AF)", "What measures can slow or prevent the progression of Atrial Fibrillation (AF)?") were considered sufficiently comprehensive and exhaustive and were retained. They were also considered minimum to assess understanding of AF, natural progression, risk factors and key components of contemporary AF management.

Table 1 provides an in-depth explanation of the questionnaire modifications at each phase, including which items were excluded and those newly developed. For example, in the section "What measures can slow or prevent the progression of Atrial Fibrillation (AF)?", "Reducing energy drink intake" and "Abstaining from coffee" were added during Phase 1 (due to recommendations from the expert advisory group), while these same items were recommended to be excluded during Phase 2 by the consumer advisory group. The consensus among the research team was to exclude these items.

3.1. Expert focus group (phase one)

The modifications based on the expert advisory group were largely related to the clinical and/or scientific merit of the items included in the AFHLQ but also provided feedback on item clarity and questionnaire acceptability (Table 1). In total, 9 items were added, one removed and replaced by another 2 items and 14 modified to improve content and item clarity. Experts provided important insights regarding the use of 'blood thinner' terminology and item modifications clarified the difference between blood thinners, aspirin, and oral anticoagulants to assess patient understanding or misunderstanding of AF management. For example, regarding the original item "Blood thinners reduce the risk of stroke", one of the experts recommended that this item should be divided into two new items since oral anticoagulant, and not aspirin, is the recommended treatment of choice to reduce stroke risk among patients with AF. This recommendation resulted in splitting the original item ("Blood thinners reduce the risk of stroke") into the two items "Aspirin reduces the risk of stroke associated with AF" and "Oral anticoagulants reduce the risk of stroke associated with AF" (items 29, 30).

Experts identified additional comorbidities that require patient management by patients to slow the progression of AF not included in the original questionnaire. For example, the original questionnaire did not include items related to knowledge about the management of thyroid disorder as important comorbidities. The two items, "Diabetes management" (item 46) and "Management of overactive thyroid" (item 47), were then included in the "What measures can slow or prevent the progression of Atrial Fibrillation (AF)?" section. The expert focus group also recommended that the term "patient with AF" should be preferred over the term "AF patients" so we avoid terms in which the medical

condition defines the individual (“AF patients”) but rather use terms that indicates that the individual is experiencing the medical condition (“patient with AF”).

3.2. Consumer focus group (phase two)

Consumers provided feedback on several components of the AFHLQ (Table 1) leading to modification of 21 items and removal of 7 items. These included changes in response categories and terminology. The consumers argued that a 3-point response scale would better measure their health literacy about AF compared to the 5-point scale (Table 1, response categories). For example, in the section “What are the symptoms of Atrial Fibrillation (AF)?”, the response categories to the item “Irregular pulse” should be “Yes” (i.e. “Yes, irregular pulse is a symptom of AF”) or “No” (i.e. “No, irregular pulse is not a symptom of AF”) indicating the conciseness of the statement, instead of categories such as “Strongly Agree” (i.e. “I strongly agree that irregular pulse is a symptom of AF”) or “Disagree” (i.e. “I disagree that irregular pulse is a symptom of AF”) that indicates the strength of belief. It was determined at the follow up research team discussion that “Don’t know” was more decisive than “unsure” therefore would replace “unsure”.

The consumers recommended spelling out AF at the heading of each of the five sections to improve item clarity. Furthermore, contrary to the expert advisory group suggestion to utilise the term “medical practitioner” as a standard term for health professionals across the questionnaire, the consumers recommended that the term “health provider” was more acceptable and accurate. For example, the item wording suggested by the experts “When patients with AF seek treatment or buy medication, they should tell the *medical practitioner* [emphasis added] that they take blood thinners regularly” was modified based on consumers recommendations to “When patients with AF are prescribed other medications, they should tell the *health provider* [emphasis added] that they take oral anticoagulants”. In the former, the term “medical practitioner” would refer mostly to physicians and general practitioners, while in the latter the term “health provider” is broader and encompasses other health professionals (nurses, pharmacists, and allied health professionals).

Further recommendations were made to improve item clarity and questionnaire acceptability. For example, while experts suggested using medical terms followed by lay terms throughout the questionnaire (Table 1, item 31,35 and 40), the consumers suggested the opposite and stressed the importance of using instead lay terms followed by medical terms in brackets to ensure patient understanding.

Other modifications suggested from the consumer advisory group were also related to terminology clarification and readability from the consumer perspective (Table 1, items 6, 30, 32, 37). For example, while the expert advisory group suggested the addition of ‘BP machine’ to the item ‘AF can be identified by regularly checking the pulse yourself, or with a smartwatch or BP machine,’ the patients emphasized the need to clarify that the acronym “BP” is referring to “blood pressure”. Therefore, the final item reads, ‘AF can be identified by regularly checking the pulse yourself, or with a smartwatch or blood pressure machine.’ Similar suggestions were given for the terms “stool” and “abstaining”, which were changed to “bowel motions” and “stopping”, respectively.

The consumers also proposed modifications to wording common to several items, particularly in the “What measures can slow or prevent the progression of Atrial Fibrillation (AF)?” section, where experts had placed ‘where applicable’ in brackets following items regarding the management of health conditions (Table 1, items 41, 43–45, 46 and 47). For example, the experts recommended items in that section to be worded as “Blood pressure control (where applicable)” or “Weight loss (where applicable)”. The consumers emphasized that, the items were easier to understand from a consumer perspective without including the ‘where applicable’ term.

3.3. Final AFHLQ questionnaire

The final 47-item instrument consisted of 5 domains (Table 2). There were 10, 9, 9, 12 and 7 items respectively in these five domains. The instrument had the correct response as ‘Yes’ for 33 items and ‘No’ for 14 items. The correct response was ‘No’ for items 2, 9, 15, 20, 22, 23, 25, 28, 29, 31, 32, 33, 34, and 39.

4. Discussion

Despite being a global pandemic, patient with AF not only lack understanding of their disease and are inadequately satisfied by the treatment, but their doctors also find this condition difficult and time consuming to manage [14]. The current study was undertaken due to lack of comprehensive PROMs to guide on AF specific health literacy. Such instruments are important as personal behaviour change is potentially a key to the effective management of AF, to slow or prevent disease progression, and for the mitigation of AF-related complications. Previous instruments such as those focusing on warfarin knowledge have reduced utility with wider use of novel oral anticoagulants [15]. Others address symptoms and knowledge in general [16,27]. However, the last decade has established the role of risk factor management in comprehensive care of patients with AF which is not addressed in previous instruments [6,16,27–29] with a predominant focus on oral anticoagulation. Our aim was to conduct a comprehensive development and qualitative validation of the Atrial Fibrillation Health Literacy Questionnaire (AFHLQ), incorporating recommendations from both experts and consumers to the final questionnaire. The AFHLQ was designed to inform the health literacy of patients with AF, highlighting topics in which people with AF often have insufficient knowledge and misconceptions. To the best of our knowledge, this is the first comprehensive PROM with a focus to assess knowledge on risk factors for AF. It not only assesses understanding of AF and treatment options, but also patient’s understanding on risk factors for AF and benefits of managing them.

The findings of the current study showed that the original 47 item pool developed by the research team, composed of researchers, physicians, and nurses with expertise in AF was modified after input from expert and consumer advisory groups. Firstly, the consultative process demonstrated that the content validity and construct representativeness of the original items, developed by members of the research team with expertise in AF, was improved once the opinion of a broader group of experts was considered (e.g., Table 1, item 10, 19, 29, 30, 34, 40 and 47). Secondly, the findings emphasized the importance of consulting with consumers. For example, while the version of the AFHLQ discussed during the consumer advisory group was clinically and scientifically accurate, the consumers indicated several ways to improve the questionnaire to clarify items and improve upon face validity of the questionnaire from their perspective. The Likert scale for responses was changed to ‘yes, no, don’t know’. Both the expert and consumer groups found questions acceptable and questionnaire length appropriate. The entire process of qualitative validation of the AFHLQ questionnaire highlighted the importance of the early stages of questionnaire development, such as clearly defining the construct and target population, construction of an item list, and qualitative validation with stakeholders (experts and consumers) to ensure the questionnaire construct validity (specifically content validity, face validity and construct representativeness) prior to the application to a large sample and subsequent quantitative psychometric validation.

The strengths of the study include the comprehensive questionnaire development and validation conducted with both expert and consumer groups, conducted in accordance with current methodological recommendations for qualitative validation [25]. Further validation is being undertaken to report on structural validation and internal consistency of the various domains and reliability of the AFHLQ in a large cohort of patients with AF. The limitations include potential bias due to

convenience sampling [21]. Individuals who agree to participate in research studies usually have a higher educational attainment [30]. It is possible that the consumers with AF who agreed to participate in the advisory groups had better AF literacy compared to participants who did not participate in our study. In this case, the consumers involved in the advisory group might have indicated that the AFHLQ items were easy to understand, while certain AFHLQ items might remain unclear for consumers who did not agree to participate.

Unlike previous AF knowledge instruments [6,16,28,29], this questionnaire tests the awareness the risk factors for AF and their management. It also assesses the understanding of the patient on the natural history of the disease. The AFHLQ has a potential for both research and clinical application. It is designed not only to evaluate the AF specific health literacy and personalised management of patients with AF but also as a semi-quantitative tool to assess change in interactive and critical literacy after educational interventions.

5. Conclusion

The development of a questionnaire to measure AF literacy is essential to elucidate the health literacy levels of people living with AF and understanding areas for improvement and common misconceptions regarding the disease. This information will guide interventions at a clinical and population level to improve AF health literacy. A future report will field-test the AFHLQ in a large sample of participants with AF to quantitatively confirm the current findings regarding face and content validity, acceptability, item comprehension, among other psychometric properties.

Credit authorship contribution statement

Gai McMichael: Data curation, Formal analysis, Investigation, Writing – original draft. **Lynette Cusack:** Formal analysis, Methodology, Validation. **Dian Andina Munawar:** Writing – review & editing. **Mark Boyd:** Writing – review & editing. **Lyle Palmer:** Writing – review & editing. **Han S Lim:** Writing – review & editing. **Rajiv Mahajan:** Conceptualising, Data curation, Formal analysis, Investigation, Methodology, Validation, Writing – original draft, review and editing and approving final draft.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijcha.2023.101322>.

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