

Developing questionnaires in clinical research

4 Oct 2014 – Dr Dawn Aitken, PhD

Questionnaires

- This session will cover how to choose appropriate questionnaires for population health research and things to think about when developing your own questionnaire to use in a research study

Collecting data

- Researcher/research assistant (RA) forms
 - ▣ Data collection form

Pulse Wave Velocity

Supine Standing Side: ☐ Left ☐ Right

Sternal notch to carotid pulse: mm mm

Sternal notch to femoral pulse: mm mm Measure: ☐ Tape ☐ Calliper

Supine	Reading 1		Reading 2		Average	
	SBP (mmHg)	DBP (mmHg)	SBP (mmHg)	DBP (mmHg)	SBP (mmHg)	DBP (mmHg)
Brachial BP at 3 minutes	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Central (Xcel) BP at 3 minutes	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
PWV > 3 minutes	<input type="text"/>	<input type="text"/> m/s	<input type="text"/>	<input type="text"/> m/s	<input type="text"/>	<input type="text"/> m/s

Standing	Reading 1		Reading 2		Average	
	SBP (mmHg)	DBP (mmHg)	SBP (mmHg)	DBP (mmHg)	SBP (mmHg)	DBP (mmHg)
Brachial BP at 2 minutes	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Central (Xcel) BP at 2 minutes	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
PWV > 2 minutes	<input type="text"/>	<input type="text"/> m/s	<input type="text"/>	<input type="text"/> m/s	<input type="text"/>	<input type="text"/> m/s

24 Hour Ambulatory Blood Pressure

Device number:

Arm: ☐ Left ☐ Right

	Awake		Asleep		Overall	
	SBP (mmHg)	DBP (mmHg)	SBP (mmHg)	DBP (mmHg)	SBP (mmHg)	DBP (mmHg)
Brachial	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Central - standard calibration	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Central - MAP & DBP calibration	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Was your sleep disturbed by the 24 hour ABPM? Not at all ☐

 A bit ☐

 A lot ☐

 Couldn't sleep at all ☐

- Participant/patient questionnaires
 - ▣ Self-report questionnaire

SF36 - Section 1

1 In general, would you say that your health is:

Excellent ☐

Very good ☐

Good ☐

Fair ☐

Poor ☐

2 Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago ☐

Somewhat better now than one year ago ☐

About the same as one year ago ☐

Somewhat worse now than one year ago ☐

Much worse now than one year ago ☐

3 The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Activity	Yes Limited a lot	Yes Limited a little	Not limited at all
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Lifting or carrying groceries	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Climbing several flights of stairs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Climbing one flight of stairs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Bending, kneeling or stooping	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. Walking more than one kilometre	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h. Walking several blocks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i. Walking one block	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j. Bathing or dressing yourself	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Purpose of questionnaires/forms

- Collect data
 - ▣ Systematic and efficient way
 - ▣ Valid way
 - ▣ Reliable way
 - ▣ Responsive to change

Data collection form

INCLUSION CRITERIA

1. Date of Birth and Age

Date of Birth: / /

Age (calculate from DOB): years

DOES SUBJECT MEET INCLUSION CRITERIA?
(must be aged between 18 and 70)

☐ No ☐ Yes

2. Antihypertensive medication

Months on antihypertensive medication: months

DOES SUBJECT MEET INCLUSION CRITERIA?
(must be on antihypertensive medication for at least 1 month)

☐ No ☐ Yes

3. Antihypertensive medication (including diuretics)

List below any antihypertensive medications the subject is currently taking

Medication	Class	Combination drug
		<input type="radio"/> No <input type="radio"/> Yes
		<input type="radio"/> No <input type="radio"/> Yes
		<input type="radio"/> No <input type="radio"/> Yes
		<input type="radio"/> No <input type="radio"/> Yes
		<input type="radio"/> No <input type="radio"/> Yes

Number of antihypertensive medications:
(a combination drug counts as 2 medications)

DOES SUBJECT MEET INCLUSION CRITERIA?
(must be on at least 1 but no more than 3 antihypertensive medications)

☐ No ☐ Yes

List below any other prescribed medications the subject is currently taking

EXCLUSION CRITERIA

A subject will NOT be eligible for study participation if he/she meets any of the following criteria.
Stop screening as soon as a subject is ineligible and thank them for participating in the call.

1. Pregnancy

Subject is pregnant, breastfeeding or planning on becoming pregnant. ☐ No ☐ Yes

Notes:

2. Concomitant therapy

Subject is undertaking concomitant therapy with both ACEi and ARB drugs. ☐ No ☐ Yes

Notes:

3. Taking digoxin, lithium or nondepolarising muscle relaxants

Subject is taking digoxin or lithium or nondepolarising skeletal muscle relaxants (e.g. Tubocurarine).

☐ No ☐ Yes

Notes:

4. Aldosterone inhibitor

Subject is taking aldosterone inhibitor (epiirenone, spironolcatone) within 30 days of enrolment

☐ No ☐ Yes

Notes:

5. Potassium supplements

Subject is taking potassium supplements or potassium sparing diuretics (e.g. amiloride or trimterene)

☐ No ☐ Yes

Notes:

6. Coronary artery disease

Subject has coronary artery disease. ☐ No ☐ Yes

Notes:

5. The list below shows the medications you were taking three months ago, as noted on your previous questionnaires

Atorvastatin 50 mg once per day
Celebrex 100 mg twice per day

Please list in the box below any **changes** to the above medications, particularly anti-inflammatory or pain medication. Please include the medication name, dose and frequency (e.g. 2 tablets twice a day), and the reason for new use or medication change.

Knee WOMAC Questionnaire

Please answer the following questions by placing an "x" through the horizontal line.

1. KNEE PAIN

What amount of knee pain have you experienced in your knee in the last seven days during the following activities?

- a. Walking on a flat surface

None _____ Unbearable

Office
use only

--	--	--

- b. Going up and down stairs

None _____ Unbearable

--	--	--

- c. At night while in bed

None _____ Unbearable

--	--	--

- d. Sitting or lying

None _____ Unbearable

--	--	--

- e. Standing upright

None _____ Unbearable

--	--	--

2. KNEE FUNCTION

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in your knee in the last seven days?

- a. Descending stairs

None _____ Unbearable

--	--	--

- b. Ascending stairs

None _____ Unbearable

--	--	--

- c. Rising from sitting

None _____ Unbearable

--	--	--

- d. Standing

None _____ Unbearable

--	--	--

- e. Bending to floor / Picking up an object

None _____ Unbearable

--	--	--

ADVERSE EVENTS

Please complete a new form for each adverse event.
Areas shaded in grey are to be completed by the Principal Investigator

A randomised trial of zoledronic acid for osteoarthritis of the knee

Hobart ☐
Melbourne ☐
Adelaide ☐
Sydney ☐

Participant ID:

Participant Initials:

Staff Initials:

Date: / /

Please give a full description of the adverse event:

Start Date: / /

Time: :

Stop Date: / /

Time: :

Intensity:

Mild ☐

Symptom(s) barely noticeable to the patient or does not make the patient uncomfortable. The AE does not influence performance or functioning. Prescription drugs are not ordinarily needed for relief of symptom(s).

Moderate ☐

Symptom(s) of a sufficient severity to make the patient uncomfortable. Performance of daily activities is influenced. Treatment of symptom(s) may be needed.

Severe ☐

Symptom(s) of a sufficient severity to cause the patient severe discomfort. Severity may cause cessation of treatment with the drug. Treatment for symptom(s) may be given.

Unlikely ☐

Relationship to study medication
To be determined by the Principal Investigator

Possible ☐

Probable ☐

Definite ☐

Was the adverse event **serious**? No ☐ Yes ☐

Did the adverse event result in death, was it life threatening, require admission to hospital or prolong hospitalisation?

Type of serious adverse event:

Death ☐

Life-threatening ☐

(ie, in the opinion of the investigator, the subject is at immediate risk of death from the AE)

Required inpatient admission or prolongation of existing admission (admission not elective) ☐

Resulted in persistent or significant disability/incapacity ☐
(a substantial disruption of the subject's ability to conduct normal life functions)

Constitutes an important medical event eg cancer ☐

Did the participant take any medications for this adverse event? No ☐ Yes ☐

Name	Dose	Freq.	Route	
				Start: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Stop: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
				Start: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Stop: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Is this event an expected side effect, or a known endpoint? No ☐ Yes ☐

Did the participant continue in the study? No ☐ Yes ☐

Type of report? Initial ☐ Final ☐

Has this been reported to the local ethics committee? No ☐ Yes ☐

PI Signature: _____ Date: / /

1. Height

Stadiometer Type:

Number:

Time height measured (24 hour time) :

Height . cm

2. Weight

Scale Type:

Number:

Weight: . kg

3. Leg muscle strength

Measurement 1: kg

Measurement 2: kg

Based on the "Participant CRF - Six month data collection" form, complete the following questions:

4. Did the participant note any changes to their medicine use? ☐ No ☐ Yes

If 'Yes', please ensure this section is complete with medication name, dose, frequency and reason for use/change.

5. Did the participant sustain any adverse events during the last three months? ☐ No ☐ Yes

If Yes,
what was the number of adverse events the participant sustained:

Has an adverse events form been completed?

☐ No ☐ Yes

Were there any serious adverse events?

☐ No ☐ Yes

If Yes,
how many serious adverse events did the participant sustain?

6. Knee WOMAC and VAS form completed? ☐ No ☐ Yes

7. AQL form completed? ☐ No ☐ Yes

Participant/Patient Self-report Questionnaires

- Number 1 Rule: Don't re-invent the wheel
- Chances are someone has already developed a questionnaire which would suit your purpose or that you could modify slightly to be appropriate for your study
- When choosing what questionnaire to use:
 - ▣ Validity: Has it been validated?
 - ▣ Reliability: Is it reliable?
 - ▣ Responsive to change
 - ▣ Research setting: Consider your sample
- E.g. Quality of Life

Quality of Life

- AQoL¹: The Assessment of Quality of Life questionnaire
- Assesses health related quality of life
- Initially designed for use in economic evaluation studies
- Generate utility scores which assess change in health status and preferences for specific health-related outcomes; therefore providing cost-effectiveness data
- Four AQoL instruments have been developed:

Instrument	Items	Completion time	Dimensions included
AQoL-8D	35	~ 5 min	Independent Living, Happiness, Mental Health, Coping, Relationships, Self Worth, Pain, Senses
AQoL-7D	26	3-4 min	Independent Living, Mental Health, Coping, Relationships, Pain, Senses, Visual Impairment
AQoL-6D	20	2-3 min	Independent Living, Mental Health, Coping, Relationships, Pain, Senses
AQoL-4D	12	1-2 min	Independent Living, Mental Health, Relationships, Senses


- Free: No license fee or cost for downloading

1. Hawthorne G, Richardson J, Osborne R. The Assessment of Quality of Life (AQoL) instrument: a psychometric measure of health-related quality of life. Qual Life Res. 1999;8:209-24.

<http://www.aqol.com.au/index.php/validation-faqs>

tion

SF36 - Google Search



[HOME](#) [INSTRUMENTS](#) [FAQS](#) [CITING AQOL](#) [REGISTER YOUR STUDY](#) [CURRENT RESEARCH](#) [CONTACT US](#)

Validation

- ▶ [What is validation?](#)
- ▶ [Validation in practice](#)
- ▶ [Validity and parsimony](#)
- ▶ [Categorising Tests of Validity](#)

Some Common Issues

- ▶ [Face Validity and Construct Validity](#)
- ▶ [The need for multiple items](#)
- ▶ [Does correlation demonstrate validity](#)
- ▶ [Economics vs psychometrics: The GDP dilemma](#)
- ▶ [Decision analytic vs psychometric valuation](#)
- ▶ [Combining DA and PI in MAU instruments](#)

Validating MAU instruments

- ▶ [How is an MAU instrument validated?](#)
- ▶ [Necessary and sufficient conditions for QALY validation](#)
- ▶ [Have MAU instruments been satisfactorily validated?](#)
- ▶ [Do MAU instruments correlate highly](#)
- ▶ [Why do MAU instruments have a low correlation?](#)
- ▶ [Why is modelling necessary: have utility models been validated?](#)
- ▶ [Validating Utility \(Scaling Instruments\)](#)
- ▶ [Can there be Negative Utilities?](#)

Validity of the AQoL Instruments

- ▶ [Why is another instrument necessary](#)
- ▶ [Have AQoL utility scores been validated](#)
- ▶ [Have the AQoL instruments been validated](#)

MIC Description

- [Multi-Instrument Comparison study](#)
- [MIC questionnaire](#)
- [Brochures & Papers](#)
- [Presentations](#)
- [Request data](#)

Information

- [What is AQoL?](#)
- [Choice of Instrument: Why AQoL?](#)
- [Background](#)
- [Research Papers](#)
- [Validation](#)
- [QoL Links](#)
- [AQoL Users](#)
- [Online TTO](#)

Using AQoL

- [Which AQoL?](#)
- [Instruments](#)
- [Scoring](#)
- [Norms](#)
- [Transformations](#)
- [Translations](#)
- [Citing AQoL Instruments](#)
- [Publications using AQoL](#)

The measurement of quality of life in hypertensive patients: a practical approach

C. J. BULPITT & A. E. FLETCHER

Division of Geriatric Medicine, Hammersmith Hospital, Du Cane Road, London W12 0HS

Section 1

1. In the last month have you suffered from lightheadedness or faintness? YES ☐ NO ☐
If NO, please go to question 4
2. If YES, does the lightheadedness or faintness occur only when you are standing? YES ☐ NO ☐
3. For how many hours in the day are you troubled by lightheadedness or faintness?
Less than one hour ☐
1–2 hours ☐
More than 2 hours ☐
4. In the last month have you often felt sleepy during the day? YES ☐ NO ☐
5. How many hours per 24 do you usually sleep? HOURS
6. Have you in the last month noticed weakness in the limbs? YES ☐ NO ☐
7. Have you in the last month had blurring of vision? YES ☐ NO ☐

Scoring of Health Index (Appendix B)

i) Disablement

Score 0.625 when 'unemployed for medical reasons' (Q36).

ii) Major disability

Score 0.75 when patient unable to go to work for more than 3 days in the last month (Q37) or to do usual jobs around the house for this period (Q39).

iii) Minor disability

Score 0.8 when high blood pressure or treatment interfered with hobbies (Q44) or life (Q46).

iii) Discomfort

Score 0.875 when not allocated to one of the above activity states yet, on average, the patient had more than 30% positive answers to the qualitative questions on symptoms (Q1–30).

Minor dissatisfaction. Score 0.975 when not allocated to any of the above activity states and the patient had less than 30% positive answers to the questions on symptoms.

The score recorded is the lowest of the above scores. Please note, if patient has died, score 0; confined to bed, score 0.125; and confined to the house but not to bed, score 0.375.

LOW CBP Study: Home BP Diary

Site ID: Subject ID:

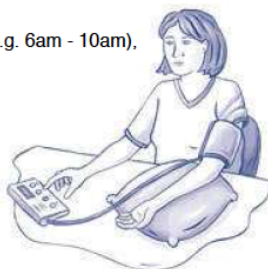
Participant:

Device Number:

Arm: ☐ Left ☐ Right

Time Point: ☐ Baseline ☐ 6 months ☐ 12 months ☐ 18 months ☐ 24 months

We are asking you take your blood pressure (BP) every morning (e.g. 6am - 10am), midday and evening (e.g. 6pm - 10pm) for 7 days. It is important that you follow the steps show below.



Please take your BP

- Before taking medication and before eating
- 30 minutes clear of smoking or caffeine

How to position yourself to take your BP?

- Sit in a chair with your back supported, arms and legs uncrossed, feet flat on the floor.
- Wrap the cuff around your upper arm as shown in the diagram
- Ensure the cuff is at about the level of the heart, which can be achieved by supporting on a table for example.

How to take your BP?

- Readings should be taken in a warm, comfortable, quiet place without distractions of television, loud music or people talking.
- Rest for 5 minutes, then press the button to take BP.
- Record the BP measurements in the "Reading 1" row of the BP diary on the back of this page. Write the systolic and diastolic readings in the appropriate columns for each period of each day of the week. Please ensure you record the values on the row for the correct day of the week.
- After about 30 seconds, repeat the measurement and record in the "Reading 2" row of the diary.

Other points

- Please record over the page the date you start recording your blood pressures.
- If necessary, please make comments over the page regarding any unusual events that may have affected your BP readings.
- Please remember that the monitor provided is for your use only.

3805579704

LowCBP BP Diary V3

Starting Date: / /

	Morning		Midday		Evening	
	SBP	DBP	SBP	DBP	SBP	DBP
Day 1	Reading 1: <input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>	
	Reading 2: <input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>	
Day 2	Reading 1: <input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>	
	Reading 2: <input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>	
Day 3	Reading 1: <input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>	
	Reading 2: <input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>	
Day 4	Reading 1: <input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>	
	Reading 2: <input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>	
Day 5	Reading 1: <input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>	
	Reading 2: <input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>	
Day 6	Reading 1: <input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>	
	Reading 2: <input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>	
Day 7	Reading 1: <input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>	
	Reading 2: <input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>		<input type="text"/> / <input type="text"/>	

Comments

4622579702

LowCBP BP Diary V3

How to administer questionnaires

- Postal survey/mail out
- Telephone survey
- Face-to-face
 - In the clinic
 - Bring in questionnaire for checking
- Web-based
- Mobile devices

Measuring pain

Knee Pain VAS - Self Assessment

Please answer the following questions by placing an "x" through the horizontal line.

Assessment of knee pain.

On this line, thinking about your **left** knee, where would you rate your pain?
Use the last seven days as a time frame.

*Office
use only*

None

Unbearable

--	--	--

If you are writing the questions

- Wording, terminology
- Sequence and structure. Avoid repetition but be thorough
- Length
- Pilot, Pilot, Pilot