

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 Measure: Tape Calliper

Sternal notch to carotid pulse: mm mm

Sternal notch to femoral pulse: mm mm

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"/>					
Central (Xcel) BP at 3 minutes	<input type="text"/>					
PWV > 3 minutes	<input type="text"/>					

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"/>					
Central (Xcel) BP at 2 minutes	<input type="text"/>					
PWV > 2 minutes	<input type="text"/>					

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"/>					
Central - standard calibration	<input type="text"/>					
Central - MAP & DBP calibration	<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 (epiereone, 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?

- Office use only*
- a. Walking on a flat surface
None _____ Unbearable
 - 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.

Relationship to study medication

To be determined by the Principal Investigator

Unlikely

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. AQoL 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

The screenshot shows the 'validation-faqs' page on the AQoL website. The page has a dark blue header with the AQoL logo and a search bar. Below the header is a navigation menu with links for HOME, INSTRUMENTS, FAQs, CITING AQOL, REGISTER YOUR STUDY, CURRENT RESEARCH, and CONTACT US. The main content area is divided into several sections, each with a title and a list of expandable items. On the right side, there is a sidebar with three sections: MIC Description, Information, and Using AQoL, each with a list of links.

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

Survey - Cost of Haemochromatosis | Haemochromatosis Australia

haemochromatosis.org.au/survey-cost-of-haemochromatosis/

Bookmarks Reading List

- Hobart Forecast
- Current hobart temperature - ...
- Home - AFL Tasmania
- ISI Web of Knowledge
- ISI Web of Knowledge - Citations
- Tasmanian Community Fund L...
- CloudStor
- MyState - Banking, Loans, Inve...
- ORCID
- ResearcherID.com
- iGRad - Graduate Research - U...
- Menzies Homepage
- Menzies Staff & Student Direct...
- LTAS - WARP
- Web Kiosk - University of Tasm...
- Menzies Intranet New
- eJournals - Library - University...
- UTas Internal Funding - Resear...
- Promotions - UTas - accelerate...
- Visiting Fellows & Visiting Scho
- iGRad - inSite - Supervisor Log...
- New Travel Agent UTas - Ardr...
- Ethics - meetings and submissi...
- Consent etc template
- Serko@ Online - Login
- NEAF
- Document Delivery
- NHMRC Outcomes of funding r...
- RGMS

Researchers at the Menzies Research Institute Tasmania are conducting a study into the costs related to having haemochromatosis. This is part of a larger project that will investigate cost-effective screening programs. Such programs aim to reduce the number of people who develop health problems due to iron overload.



The researchers are interested in hearing from as many people as possible who have been diagnosed with haemochromatosis.

Haemochromatosis Australia supports the research and ask you to spare a little time to help understand the costs of this condition.

Who can participate: anyone living in Australia who has been diagnosed with haemochromatosis aged 18 years or older. It doesn't matter if you experience no health problems or if you experience quite a few related to haemochromatosis.

What is involved: There are two parts to this study:

First, an online survey looking at health, employment, income and private health insurance.

After this, we will ask you to complete a 'Cost Diary' once per month for three months. This will involve recording recent use of any health services (e.g. doctor's appointments, blood tests, venepuncture) or medications, and the costs (if any) of these.

How: [Visit the survey website here.](#)

◀ Previous Entry Next Entry ▶

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

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If you are writing the questions

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

- Pilot, Pilot, Pilot