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

- Participant/patient questionnaires
  - Self-report questionnaire
Purpose of questionnaires/forms

- Collect data
  - Systematic and efficient way
  - Valid way
  - Reliable way
  - Responsive to change
Data collection form

### Inclusion Criteria

<table>
<thead>
<tr>
<th>1. Date of Birth and Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Birth: [ ] / [ ] / [ ]</td>
</tr>
<tr>
<td>Age (calculate from DOB): [ ] years</td>
</tr>
</tbody>
</table>

**Does subject meet inclusion criteria?** (must be aged between 18 and 80)

- [ ] No
- [ ] Yes

<table>
<thead>
<tr>
<th>2. Antihypertensive medication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Months on antihypertensive medication: [ ] months</td>
</tr>
</tbody>
</table>

**Does subject meet inclusion criteria?** (must be on antihypertensive medication for at least 1 month)

- [ ] No
- [ ] Yes

<table>
<thead>
<tr>
<th>3. Antihypertensive medication (including diuretics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>List below any antihypertensive medications the subject is currently taking</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication</th>
<th>Class</th>
<th>Combination drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

Number of antihypertensive medications: [ ] (a combination 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.

<table>
<thead>
<tr>
<th>1. Pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject is pregnant, breastfeeding or planning on becoming pregnant</td>
</tr>
</tbody>
</table>

**Notes:**

<table>
<thead>
<tr>
<th>2. Concomitant therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject is undertaking concomitant therapy with both ACEi and ARB drugs</td>
</tr>
</tbody>
</table>

**Notes:**

<table>
<thead>
<tr>
<th>3. Taking digoxin, lithium or nondepolarising muscle relaxants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject is taking digoxin or lithium or nondepolarising skeletal muscle relaxants (e.g. Tubocurarine)</td>
</tr>
</tbody>
</table>

**Notes:**

<table>
<thead>
<tr>
<th>4. Aldosterone inhibitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject is taking aldosterone inhibitor (spirolone, spironolactone) within 30 days of enrolment</td>
</tr>
</tbody>
</table>

**Notes:**

<table>
<thead>
<tr>
<th>5. Potassium supplements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject is taking potassium supplements or potassium sparing diuretics (e.g. amiloride or triamterene)</td>
</tr>
</tbody>
</table>

**Notes:**

<table>
<thead>
<tr>
<th>6. Coronary artery disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject has coronary artery disease</td>
</tr>
</tbody>
</table>

**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
   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 O
Melbourne O
Adelaide O
Sydney O

Participant ID: __________
Participant Initials: __________
Staff Initials: __________
Date: __________ / __________ / __________

Please give a full description of the adverse event:

Start Date: __________ / __________ / __________
Stop Date: __________ / __________ / __________
Start Time: __________
Stop Time: __________

Intensity:

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

Moderate O
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 O
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

Unlikely O
To be determined by the Principal Investigator

Possible O
Probable O
Definite O

Was the adverse event serious?

No O
Yes O

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

Type of serious adverse event:

Death O
Life-threatening O

(required 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) O

Resulted in persistent or significant disability/incapacity O

(a substantial disruption of the subject's ability to conduct normal life functions)

Constitutes an important medical event eg cancer O

Did the participant take any medications for this adverse event?

No O
Yes O

Name Dose Freq. Route

Start: __________ / __________ / __________
Stop: __________ / __________ / __________

Start: __________ / __________ / __________
Stop: __________ / __________ / __________

Is this event an expected side effect, or a known endpoint?

No O
Yes O

Did the participant continue in the study?

No O
Yes O

Type of report?

Initial O
Final O

Has this been reported to the local ethics committee?

No O
Yes O

Pt 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. AQLQ 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

- **AQoL**⃣: 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:

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Items</th>
<th>Completion time</th>
<th>Dimensions included</th>
</tr>
</thead>
<tbody>
<tr>
<td>AQoL-8D</td>
<td>35</td>
<td>≈ 5 min</td>
<td>Independent Living, Happiness, Mental Health, Coping, Relationships, Self Worth, Pain, Senses</td>
</tr>
<tr>
<td>AQoL-7D</td>
<td>26</td>
<td>2-4 min</td>
<td>Independent Living, Mental Health, Coping, Relationships, Pain, Senses, Visual Impairment</td>
</tr>
<tr>
<td>AQoL-6D</td>
<td>20</td>
<td>2-3 min</td>
<td>Independent Living, Mental Health, Coping, Relationships, Pain, Senses</td>
</tr>
<tr>
<td>AQoL-4D</td>
<td>12</td>
<td>1-2 min</td>
<td>Independent Living, Mental Health, Relationships, Senses</td>
</tr>
</tbody>
</table>

- Free: No license fee or cost for downloading

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 ☐
   □ HOURS

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: [BLANK]  Subject ID: [BLANK]  Participant: [BLANK]
Device Number: [BLANK]  Arm: O Left  O Right
Time Point: O Baseline  O 6 months  O 12 months  O 18 months  O 24 months

We are asking you to 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 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.

Starting Date: [BLANK] / [BLANK] / [BLANK]

<table>
<thead>
<tr>
<th></th>
<th>Morning</th>
<th>Midday</th>
<th>Evening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reading 1:</td>
<td>[]/[]</td>
<td>[]/[]</td>
<td>[]/[]</td>
</tr>
<tr>
<td>Reading 2:</td>
<td>[]/[]</td>
<td>[]/[]</td>
<td>[]/[]</td>
</tr>
<tr>
<td>Day 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reading 1:</td>
<td>[]/[]</td>
<td>[]/[]</td>
<td>[]/[]</td>
</tr>
<tr>
<td>Reading 2:</td>
<td>[]/[]</td>
<td>[]/[]</td>
<td>[]/[]</td>
</tr>
<tr>
<td>Day 3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reading 1:</td>
<td>[]/[]</td>
<td>[]/[]</td>
<td>[]/[]</td>
</tr>
<tr>
<td>Reading 2:</td>
<td>[]/[]</td>
<td>[]/[]</td>
<td>[]/[]</td>
</tr>
<tr>
<td>Day 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reading 1:</td>
<td>[]/[]</td>
<td>[]/[]</td>
<td>[]/[]</td>
</tr>
<tr>
<td>Reading 2:</td>
<td>[]/[]</td>
<td>[]/[]</td>
<td>[]/[]</td>
</tr>
<tr>
<td>Day 5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reading 1:</td>
<td>[]/[]</td>
<td>[]/[]</td>
<td>[]/[]</td>
</tr>
<tr>
<td>Reading 2:</td>
<td>[]/[]</td>
<td>[]/[]</td>
<td>[]/[]</td>
</tr>
<tr>
<td>Day 6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reading 1:</td>
<td>[]/[]</td>
<td>[]/[]</td>
<td>[]/[]</td>
</tr>
<tr>
<td>Reading 2:</td>
<td>[]/[]</td>
<td>[]/[]</td>
<td>[]/[]</td>
</tr>
<tr>
<td>Day 7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reading 1:</td>
<td>[]/[]</td>
<td>[]/[]</td>
<td>[]/[]</td>
</tr>
<tr>
<td>Reading 2:</td>
<td>[]/[]</td>
<td>[]/[]</td>
<td>[]/[]</td>
</tr>
</tbody>
</table>

Comments

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
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, venipuncture) or medications, and the costs (if any) of these.

How: Visit the survey website here.
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.

None  ___________________________  Unbearable

Office
use only
If you are writing the questions

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