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HEDS Discussion Paper

No. 11/16

**Preparation for the Re-valuation of the EQ-5D Tariff (PRET)
project: Overview of methods for project stages 1-3**

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Preparation for the Re-valuation of the EQ-5D Tariff (PRET) project: Overview of methods for project stages 1-3

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Summary

Preparatory study for the Re-valuation of the EQ5D Tariff (PRET) and PRET - Additional Sample (PRET-AS) are two associated research projects. The aim of this methods paper is to outline the methodological issues and the study design used in these two projects. PRET has four stages, stage 1 includes an on-line survey investigating a range of methodological factors relating to health state valuation; stage 2 involves a comparison of the on-line and face-to-face administration of health state valuation questions; stage 3 uses face-to-face interviews to investigate respondents' opinions of various health state valuation methodologies, and the strategies and processes involved in answering the questions. Stage 4 refines the protocol. This methods paper addresses the first three of these four stages. In addition, PRET-AS is an on-line survey that is added to stage 1 of PRET. The programme of research will inform key aspects of the upcoming EQ-5D re-valuation studies.

Acknowledgements

PRET is funded by the MRC Methodology programme (ref.G0901500). BM is partly funded by the MRC. PRET-AS is an extension of PRET and is funded by the EuroQol Group. AT is the Principal Investigator for PRET and PRET-AS. The usual disclaimer applies.

1. Background

Health care resources are limited and need to be allocated efficiently. The National Institute for Health and Clinical Excellence (NICE) was set up to help make better health care resource allocation decisions. NICE bases its recommendations on cost effectiveness analyses with the Quality Adjusted Life Year (QALY) as the outcome measure. The QALY combines values for quality and quantity of life in a single figure. This requires a value for the health related quality of life (HRQL) or utility for a particular health state. The EQ-5D (Brooks, 1996), is the preferred instrument to use to derive a utility value to assess the HRQL impact of medical interventions (NICE, 2008). The EQ-5D assesses HRQL across five dimensions (mobility, self care, usual activities, pain/discomfort and anxiety/depression). In the original version, each EQ-5D dimension has three response levels (no, some or extreme problems).

The current UK EQ-5D value set is based on the Measurement and Valuation of Health (MVH) study. This study used face-to-face interviews of a representative sample of the UK general population to value 45 hypothetical EQ-5D states using the preference elicitation method time trade-off (TTO). The results of the valuation study were modelled to provide a utility score for all 243 EQ-5D health states (Dolan, 1997).

The UK EQ-5D value set is used for economic evaluations by a range of decision makers and researchers. They are also used in a range of further applications, including population health surveys (eg. the Health Survey for England); burden of disease studies; hospital inpatient surveys and the NHS PROMs initiative (Browne et al 2007).

The EQ-5D tariff needs to be re-validated for the following reasons:

- A five level version of the EQ-5D (EQ-5D-5L; Herdman et al., 2011) has been developed. The version does not have a population value set and will be the version for which a tariff will be derived in the re-valuation study;
- People may not have the same preferences as they did 17 years ago;
- Change in demography may mean that although individual preferences may not have changed, the composition of people across the country has changed, so that average preferences may have changed;
- Recognition of the shortcomings of the MVH TTO design, in particular in the context of observations worse than dead;
- There have been advances in health state valuation methods, including the application of Discrete Choice Experiments (DCE) in a health care context;
- There have been advances in the administration modes available for valuation studies (for example on-line)

In order for NICE to make the most appropriate decisions, the EQ-5D UK population value set needs to be up to date, based on the latest understanding of health state preferences and relevant to the EQ-5D-5L. The MRC funded project “Preparatory study for the Re-valuation of the EQ-5D Tariff” (PRET) is a methodological study that aims to contribute to the valuation of the EQ-5D-5L population value sets by exploring a range of methodological issues associated with health state valuations. Furthermore, “PRET – Additional Sample” (PRET-AS) is an extension to PRET, and is funded by the EuroQol Group.

PRET has four stages. In Stage 1, a large scale on-line survey is carried out to explore a series of methodological issues related to health state valuation. PRET-AS is an extension to Stage 1 of PRET conducting another on-line survey. In Stage 2, a segment of the on-line survey is carried out in a face-to-face environment using Computer Assisted Personal Interviewing (CAPI) to test issues related to mode of administration. Stage 3 consists of more detailed interviews where selected methodological issues including the strategies and processes used to answer health state valuation questions are investigated in more detail. Stage 4 uses interviews to refine the recommendations that may inform the upcoming valuation study. The aim of this methods paper is to give an overview of the methodological issues addressed in PRET and PRET-AS, and to outline the methods used in the first three stages of PRET, and PRET-AS.

2. Methodological issues addressed by the PRET project

The design of the valuation study for EQ-5D-5L (or any health state classification system) will need to take the following methodological issues into account:

- (1) Whose values to obtain?
- (2) What mode of administration?
- (3) What method of valuation?
- (4) How many, and which hypothetical health states to value?
- (5) How long should each hypothetical state last?

Each is discussed in more detail below.

(1) Whose values?

The EQ-5D-3L value set is based on general population values. General population values of hypothetical health states may differ from the way patients value hypothetical states or their own current state, and there has been debate about which values should be used (Brazier et al, 2005). PRET does not have the capacity to compare patient and general public values. However, a recent study has demonstrated that if the general public can be informed about the extent to which it is possible for patients to be satisfied with their condition, the discrepancy in values may diminish (McTaggart-Cowan et al, 2009). PRET examines this further by introducing an element of health satisfaction, so that the way in which patients feel about the state of health can be captured.

There is also a normative element to this debate, concerning whether general public values ought to be used over patient values. The use of general public values is typically justified with reference to the non-welfarist argument which states that as the values are used in decision making in a publicly funded health care system, they should come from people as informed citizens, not from people as consumers (see for example Tsuchiya and Miyamoto, 2009). The traditional approach to health state valuation, and that used for the current MVH value set, has been to obtain valuations by asking respondents to imagine themselves in the health state. If an informed citizen perspective is taken a different framing of the TTO question may be required to reflect that the respondent is valuing health states on behalf of other members of society. However, it is unclear what impact an alternative perspective will have on values. PRET investigates this by comparing responses using the standard individual perspective with two alternatives reflecting the citizen approach. In addition,

background characteristics questions allow for an examination of the respondent's own health and how this may impact on responses to health state valuation questions.

(2) What mode of administration?

The current MVH TTO value set is based on face-to-face interviews. Face-to-face interviews generally provide high quality data and good response rates, but they are expensive to carry out. When the MVH study was carried out, there were two more alternatives available: postal questionnaire and telephone interview (with or without a pre-posted questionnaire). While these two modes are much less costly than face-to-face interviews, they are usually regarded as resulting in lower quality data.

However, over the past decade there have been major advances in communication technology, and one attractive mode of survey administration is via the internet using on-line panels with registered background characteristics. On-line surveys allow large samples to be achieved a short time. However, they may have disadvantages associated with the representativeness of the sample, the level of non-response (Eysenbach, 2005) and the quality of the data (Bowling, 2005). Stage 1 of PRET and PRET-AS are conducted on-line. Furthermore, one of the purposes of the PRET project is to carry out a head to head comparison of an on-line administration (in Stage 1) and a CAPI administration (in Stage 2) of an otherwise identical survey.

(3) What method of valuation?

The current MVH value set is based on TTO (Gudex, 1994). The TTO protocol used to value the EQ-5D-3L has inherent problems, for example regarding the procedure used to value states worse than dead which is different to the procedure used for states better than dead (Tilling et al, 2010). An alternative TTO methodology known as 'lead time TTO' (LT-TTO) has been developed (Robinson and Spencer, 2006; Devlin et al, 2010), and work is ongoing testing the procedure. This processes all states in the same way, regardless of whether they are better or worse than dead, by adding a set number of years in full health preceding each of the health scenarios being valued. Further analysis is required to identify the optimal length of this lead time, and one of the objectives of PRET is to provide evidence on this issue. Moreover, one concern is that if the value of a health state depends on its timing and on a preceding health state, then the addition of lead time may distort the TTO value. PRET includes a comparison of the original and lead time TTO methodologies using binary choice questions as described below. Furthermore, PRET-AS examines an on-line administration of LT-TTO.

In addition to TTO, there is a growing interest in the application of DCE for health state valuations (De Bekker-Grob et al, 2010). One advantage of the DCE is that because individuals are not interrogated until they reach a point of indifference but only asked to give preferences for pairwise choices, it is arguably less cognitively demanding than TTO. On the other hand, the well-known problem with DCE has been that there is no satisfactory method of combining the dimensions of health with survival in the state. However, a method has been developed that interprets DCE data as a TTO exercise (Bansback, et al, 2010). The method includes duration as a DCE attribute and estimates regression models incorporating interaction terms between the health state dimensions and the duration attribute. PRET and PRET-AS explore this approach further.

(4) Which hypothetical health states to value?

The original 3-level EQ-5D has 243 possible states. The current MVH TTO value set is based on direct valuations of 45 of these. However, the introduction of EQ-5D-5L means that there are now 3,125 possible health states to model. Findings from the DCE questions included in PRET and PRET-AS may be used as prior information to assist in the selection of states and design of the re-valuation study.

(5) How long should each hypothetical state last?

The current MVH TTO value set is based on participants being asked to imagine each health state lasting for a duration of 10 years. However, the MVH also estimated TTO tariffs for different durations. This was because there was a concern that the tariff values may be a function of the duration of the health state. There are four related issues, all of which are also relevant to DCE (see Tsuchiya and Dolan, 2005). One is whether or not 'constant proportional time trade off' holds so that the utility associated with a marginal survival in a given health state remains constant regardless of the health state or the duration. It has been argued that for very severe states, there may be a 'maximal endurable time' limit, beyond which the marginal benefit of survival diminishes (Stalmeier et al, 2007). The second issue is whether or not respondents use a positive temporal discount rate when valuing hypothetical health scenarios. The third is the impact of life stage concerns in health state valuations. If the duration of the state is too long, then the scenarios will not be credible for older respondents and vice versa. Furthermore, depending on the duration, people may be thinking about life stage events rather than about the trade off between longevity and quality of life.

The final issue is whether or not 10 years is the most relevant duration of health states for NICE decision making. If the above issues mean that the value of a state is a function of its duration, then the re-valuation of the EQ-5D should not be based on scenarios with a 10-year duration. PRET and PRET-AS examine the impact of varying duration on health state preferences.

3. The study design used for Stage 1

3.1 *The survey question format and Types of questions in Stages 1 and 2*

The matched survey questions used for Stages 1 and 2 are binary choice. A single response to a binary choice question cannot identify the level of HRQL an individual feels is right for a given health state. However, by examining the distribution of responses of multiple respondents across different binary choice questions, identified range of methodological issues can be tested.

The most "basic" binary choice question used in PRET is as follows:

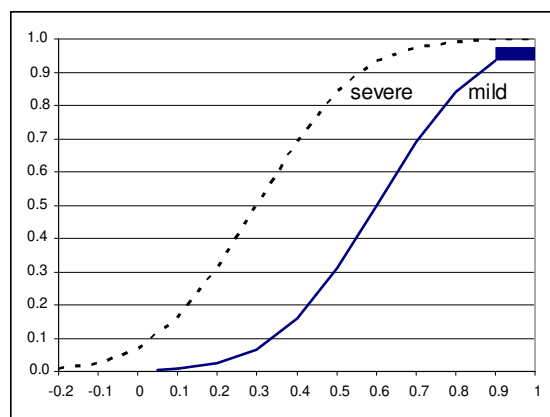
[Scenario A]: you will live in health state **H** for 10 years and die

[Scenario B]: you will live in full health for (**V** x 10) years and die (where **V** is a value between 0 and 1)

Which of the two scenarios do you think is better?

The value of V corresponds to the level of HRQL and is varied across individuals. Figure 1 is an illustrative example of two hypothetical states, “severe” and “mild”. Along the horizontal axis is the value of V with 0 for dead and 1 for full health. Along the vertical axis is the proportion of people. The upward sloping curves indicate that, as V increases, the proportion of people who think the given health state is no better than V will increase. By definition, the curve for “severe” lies to the left of a curve for “mild”. Now, suppose V is 0.6. If the state H in the example above is the severe state, then around 90% of people think it is no better than 0.6 and thus choose Scenario B. But if state H is the mild state, then around 50% will think it is no better than 0.6 and thus choose Scenario B.

Figure 1: The value of V and the proportion of respondents choosing scenario B



Thus the different health states are picked up in terms of the proportion of people choosing one scenario over the other. All binary choice scenarios will include information on a health state and the length of time lived in the state, followed by death. These binary questions could be part of a DCE design. At the same time, they are a snippet of a TTO procedure; the typical TTO exercise involves changing V until the respondent is indifferent between the two scenarios. In fact, the procedure of TTO can be interpreted as a special case of DCE, where Scenario B always involves full health.

There are seven *Types* of binary choice questions used in stages 1 and 2 of PRET and these are summarised in Table 1. Question types include one or more of the following parameters:

- EQ-5D-5L **states (H)**: see section 3.3 below
- **Duration** in years (**T**) in state H. PRET uses 10 weeks, 1 year, 5 years and 10 years.
- **Lead time** stretches (**L**) in full health including zero, 10 weeks, 1 year, 5 years and 10 years
- Person **perspective (P)** that the TTO applies to. PRET uses “you”, “somebody else like you”, “somebody else”.
- Levels of **satisfaction** with one’s own health or life (**S**). PRET uses low health satisfaction, high health satisfaction, high life satisfaction, and “learnt to live with health state”.

Table 1: The seven *Types* of questions used in Stages 1 and 2

Parameter	Question type	I	II	III	IV	V	VI	VII
State of health (H)		√	√	√	√	√	√	√
Duration in full health (T)		√	√	√	√	√	√	n/m
Duration in H		√	√	√	√	√	√	√
Lead time (L)		n/m (*)	n/m	√	√	n/m	√	n/m
Person/perspective (P)		you	other	you	other	you	you	you
Satisfaction (S)		n/m	n/m	n/m	n/m	√	n/m	n/m

(*) n/m means not mentioned in the scenario

3.2 The assumptions tested using Type I to Type V questions

The first five question Types are based on TTO, and present two scenarios:

- [A]: Person **P** lives **L** in full health followed by **T** in state **H** with satisfaction **S** then dies
- [B]: Person **P** lives (**L + VT**) in full health then dies

Scenarios in Type I use the “you” perspective and scenarios in Type II use the “other” perspective, but are otherwise identical to Type I. Scenarios in Types III and IV mention lead time **L** using the “you” and “other” perspectives respectively. Scenarios in Type V include satisfaction **S**. These questions are used to investigate the following five assumptions.

Assumption 1: health state values are independent of duration (using type I questions)

If the assumption holds, then for a given combination of state **H** and value **V**, the distribution of respondents between the two scenarios should not be affected by duration **T**. Therefore, if the duration ($10 \times V$) years in the basic scenario above was replaced with ($5 \times V$) years, the proportion of people choosing each Scenario at a given **V** should not differ.

Assumption 2: health state values are independent of person perspectives (comparing type I and II questions)

If the assumption holds, then for a given combination of state **H** and value **V**, the distribution of respondents should not differ when person perspective **P** is changed.

Assumption 3: health state values are independent of lead time (comparing type I and III questions)

If the assumption holds, then for a given combination of state **H** and value **V**, the distribution of respondents should not differ by the addition of lead time **L**.

Assumption 4: the values of others’ health are independent of when health events take place (comparing type II and IV questions)

If the assumption holds, then for a given combination of state **H**, value **V**, and perspective **P**, the distribution of respondents should not be affected by the timing of health events, represented by lead time **L**.

Assumption 5: the values of others’ health are independent of satisfaction in the state (using type V questions)

If the assumption holds, then for a given combination of state and value V , the distribution of respondents should not be affected by level of satisfaction S .

3.3 The hypothetical health states used in Type I to Type V questions

Questions Type I to V use the following five health states adapted from EQ-5D-5L:

- "Slight problems walking about" (level 2 of the mobility dimension)
- "Slight pain" (level 2 of the pain dimension)
- "Unable to walk about" (level 5 of the mobility dimension)
- "Extreme pain" (level 5 of the pain/discomfort dimension using pain only)
- "Extreme depression" (level 5 of the anxiety/depression using depression only)

Only one dimension is included in Type I to Type V questions, and therefore the health scenarios should be relatively easy to imagine. In addition, they cover different aspects of health, and therefore enable a test of the key assumptions across different hypothetical health concerns. Two sets of V values are used: 0.8 and 0.9 for the mild states ("slight") and 0.4 and 0.6 for the severe states ("unable"/"extreme"). These values are chosen based on the MVH tariff values for the five comparable health states taken from EQ-5D-3L.

3.4 Type VI questions to test the sufficiency of lead time under very poor health

Type VI questions have the following format:

- [A]: You will live L in full health followed by T in state 55555 then die
- [B]: You will die immediately

LT-TTO research has indicated that some respondents associate very poor states with extreme negative values. Therefore they will exhaust all their lead time (Devlin et al, 2011) meaning no TTO value can be derived. While at least some of these may reflect a genuine quantitative preference, others may be a qualitative indication that the state is extremely poor. Type VI questions aim to map the proportion of respondents who exhaust lead time at various combinations of duration T and lead time L . The worst possible EQ-5D-5L state 55555 (extreme problems in all five dimensions) is used for all scenario combinations.

3.5 Type VII questions for informing the selection of states for DCE

Type VII questions are a small scale DCE study and take the following form:

- [A]: You live duration T_A in state H_A then die
- [B]: You live duration T_B in state H_B then die

Both scenarios include an EQ-5D-5L state H for a specified duration T followed by death. Type VII questions are equivalent to the DCE_{TTO} developed by Bansback et al. (2010). Type VII questions are also used in PRET-AS.

3.6 The allocation of questions to questionnaire versions in PRET

Different question types are presented across three experimental *Modules*:

- Module 1: Five Type I questions
- Module 2: Five questions specific to the questionnaire version (using question Types II to VI)
- Module 3: Two Type VII questions

Each respondent is presented with 12 *binary choice questions*. There are 15 versions of the on-line questionnaire. In 14 of these, Module 2 consists of five binary choice questions from one of Types II, III, IV, V or VI, so that respondents given these versions face three question types each. However, in version 15, Module 2 consists of one question each from Types II, III, IV, V or VI. Therefore respondents allocated to version 15 complete all seven question Types. This is done so that the mode of administration can be compared across all question types at Stage 2 of the project (see section 5 below). All respondents in the face-to-face CAPI sample are given version 15, and this allows for a direct comparison between the on-line and CAPI methods.

Furthermore, there are 60 *sub-versions* (each of the 15 versions has four sub-versions) for Module 3. EQ-5D-5L has 3,125 possible health states, and combining this with three levels of duration amounts to 9,375 possible DCE scenarios. Of these, 240 are selected and paired using a D-Optimal algorithm (Mitchell, 1974) which selects states using the full factorial design as the starting point. Two of the 120 pairs are allocated to each of the 60 sub versions. The three duration levels used are 1 year, 5 years and 10 years.

3.7 Recruitment and the sample

Approximately 3000 respondents are recruited across the 60 sub-versions of the on-line survey, with each version having a minimum sample size of 50. Respondents are sourced from an existing internet panel following set quotas for age and gender to ensure that the sample is representative of the UK general population. Invitations are sent out by e-mail, and respondents are screened out prior to starting the experimental questions if the relevant quota for age and gender is complete, or after completing if they answered all of the survey questions in less than the minimum imposed time limit of 5 minutes.

3.8 Survey completion process

Each survey begins by providing a brief background explaining the purpose of the survey, and this is followed by an informed consent page which must be completed before the questions can be answered. After consenting, respondents provide demographic information and complete questions about health status, health and life satisfaction and the EQ-5D-5L. This is followed by the three experimental modules. The final page includes a free text box to enable respondents to provide their opinions on the survey or any other relevant information.

4. PRET-AS

PRET-AS is added on to Stage 1 of PRET, and includes two question types: Type VII, identical to the Type VII DCE questions used in PRET; and Type VIII, which is based on LT-TTO.

4.1 Type VIII questions used in PRET-AS

The aim of Type VIII questions is to explore whether LT-TTO can be adapted for a DCE-like binary choice presentation. The challenge for a DCE of LT-TTO is the amount of information that is involved in each choice. A DCE of LT-TTO for EQ-5D will in effect have eight dimensions per scenario (full health, lead time, the five EQ-5D dimensions, and duration in the state), totalling 16 pieces of information to consider per binary choice. Furthermore, 14 of these will change randomly from one question to the next, which seems excessive. Therefore, an alternative that is closer to the original TTO presentation is used, where scenario B always involves a shorter duration in full health. Experimental binary choice questions Type VIII took the following form:

- [A]: You will live in full health for L followed by state H for duration T then die
- [B]: You will live in full health for $(L + VT)$ then die ($V < 1.0$)

Scenario A still has eight dimensions, but scenario B only has two; of the 10 overall pieces of information, eight of them change from one question to the next. Note that the V can take negative values provided $(L + VT)$ is not negative. Similar designs have been used routinely in binary choice contingent valuation studies to elicit Willingness To Pay, and in one Standard Gamble study (Bosch et al, 1998).

The states H are hand-selected and combined with a number of levels of lead time L and value V used. Regarding the states H , five EQ-5D-3L states were used: 11211, 22121, 32211, 23232, 33333. These were selected from the 14 unique EQ-5D-3L states used so far in LT-TTO studies to reflect a combination of dimensions affected, and severity (see Devlin et al, 2010; 2011).

4.2 The logistics of PRET-AS

A further 3000 respondents are recruited for PRET-AS using the same internet survey panel and procedures as PRET. Respondents are randomly allocated to one of two groups: the first group (n=1800) are given 15 Type VII DCE questions as the main experimental questions, and the second group (n=1200) are given 10 Type VIII LT-TTO questions as the main experimental questions.

5. Stage 2

5.1 Aims of stage 2

The aim of stage 2 is to compare the on-line and CAPI administration of binary choice valuation questions, and assess differences across the modes. Version 15 of the stage 1 on-line survey is repeated in a CAPI setting presenting identical questions in the same order. In order to achieve a comparison of the two modes of administration as they would happen in the real world, the two samples are recruited separately by following procedures that would be employed in typical surveys.

5.2 Recruitment and the sample

For the CAPI component, participants are recruited by knocking on one in every ten doors in selected postcodes in five UK areas. The survey is presented to respondents on a laptop, and the interviewer reads out all of the questions and record the response. Again, participants are selected following set quotas for age and gender, and a minimum completion time of 5 minutes is imposed.

6. Stage 3

6.1 Aims of stage 3

The aim of stage 3 is to investigate and compare three types of binary choice health state valuation questions, and the strategies and cognitive processes used to answer the questions. Although health state valuations techniques such as TTO and DCE are widely used, little is known about both the external and question specific influences on respondent answers. These issues are investigated by face-to-face interviews using CAPI methodology with 300 respondents representative of the UK general population.

6.2 Question format and study design

The three binary choice question types used are: Type VII (DCE as used in Stage 1); Type VIII (binary choice LT-TTO as used in PRET-AS); and Type IX (binary choice TTO). Table 2 displays the format of the question types.

Table 2: The format of the binary choice question types used in stage 3

	Type VII: DCE_{TTO}	Type VIII: LT-TTO	Type IX: TTO
H (scenario A)	EQ-5D-5L	EQ-5D-5L	EQ-5D-5L
T (scenario A)	X years in H	X years in H	X years in H
L (scenario A)	n/m	Y years	n/m
H (scenario B)	EQ-5D-5L	Full health	Full health
T (scenario B)	X years in H	(L + V ₁ X) years	V ₂ X years

X = 1, 5 or 10 years; V₁ range -1 to 0.95; V₂ range 0.15 to 0.95

Each respondent completes two experimental *modules*, each of which consists of three examples of one of the binary choice question types followed by five probing questions. After the two experimental modules, respondents will be asked approximately 20 general feedback questions about the two types of questions they have seen. The probing and general feedback questions are developed through a series of pilot studies, and investigate strategies and processes used to answer the questions, the importance of each dimension and the influence of external factors on response, and also which question type is preferred by respondents. Six versions of the survey are developed to ensure that each question type is presented as both the first and second experimental module.

7. Summary

The development of the EQ-5D-5L and advances in the techniques used for health state valuation mean that there is the need to derive new population value set for use in cost effectiveness analysis, and a series of valuation studies will soon be carried out by the EuroQol group. The PRET and PRET-AS programmes investigate a range of methodological issues relating to the health state valuation techniques DCE and LT-TTO. The methodological issues are assessed using binary choice health state valuation questions administered using both on-line and CAPI methods. The aim of this methods paper was to give an overview of the methodological issues addressed in PRET and PRET-AS, and to outline the methods used in the first three stages of PRET, and PRET-AS. For the results and discussion of the individual studies, see their respective reports.

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