Prostate cancer is the most common cancer in men in the UK, and it is estimated that 18.5% of those diagnosed with the disease present with metastases.1 Patients who have not yet received hormone therapy, or are still responsive to hormone therapy, are classified as having metastatic hormone-sensitive prostate cancer (mHSPC). Severity of disease at diagnosis is assessed according to several prognostic factors which are associated with poorer survival. In the Phase III registration trial for abiraterone acetate plus prednisolone/prednisone in mHSPC, patients were described as having ‘high-risk’ disease if they had 2 of the following 3 prognostic factors: (1) Gleason score of ≥8; (2) presence of ≥3 lesions on bone scan; (3) presence of visceral metastasis. The standard of care for patients with mHSPC is androgen deprivation therapy (ADT) alone or docetaxel plus ADT.2,3

Patients with newly diagnosed high-risk mHSPC can experience considerable burden on their quality of life, due to side effects and symptoms, which can be relieved by strong pain palliation.4

Six AE health states were developed to describe the treatment-related AEs considered most impactful on patients’ health-related quality of life (HRQoL) as identified through the literature reviews and patient interviews. Descriptors for AEs were all combined within Base State 2 to ensure consistency in the valuation exercise. The study was granted ethics approval by an Independent Review Board in the USA.5

Validation interviews were conducted with clinicians (n=5) and a specialist nurse (n=1), who had not previously been involved in the study, to verify the health state descriptions. Following consultation on feedback from these interviews, revisions were made to the health states.

Pilot interviews were then conducted with members of the general public (n=5) to assess their comprehension of the final health states and ensure the wording was appropriate. Feedback showed the health states were well-understood and they were finalised for use in the valuation exercise. For an illustrative example, Figure 1 shows AE State for nausea and vomiting.

### Figure 1: AE State for nausea and vomiting

- You have a serious illness. You are receiving treatment, either through daily tablets or a long-acting implant placed under the skin. You also have to visit the hospital for a day once every three weeks to receive treatment via a drip.
- You sometimes experience hot flushes. You may experience tenderness and some swelling around your breast area. You have reduced sex drive and a reduced ability to have sexual relations.
- You frequently have to pass urine, both during the day and at night. You often experience bone pain, particularly in the lower part of your body. In some cases, you may have pain killers.
- You experience nausea and vomiting occasionally which lasts 2-3 days. During those days, you feel very nauseous and vomit intermittently. You receive treatment for the vomiting which could mean going into hospital for a few days.
- When you feel pain or experience nausea and vomiting, it may lead to restricted movements, such as difficulty bring down/ getting up, walking around the house, and climbing stairs. The pain or the nausea and vomiting might make it difficult to focus on your work and it can cause poor sleep.
- When you feel pain or experience nausea and vomiting, you have difficulty with washing and dressing yourself, doing jobs around the house, and shopping.
- You are rarely able to visit family and friends because of the nausea and vomiting and due to the risk of getting an infection. You often feel depressed about your condition.

### Validation study

Participants were recruited through snowball sampling and local advertising across regions in the UK. To meet the eligibility criteria, participants had to be aged 18 or over, resident in the UK, able to understand the interview, complete the protocol requirements and provide written informed consent.

Valuation exercises were conducted face-to-face with a trained TTO interviewer and participants were reimbursed for their time.

In total, participants completed a brief socio-demographic form and the EQ-SD-S1 questionnaire, and then took part in a ranking exercise. This involved the participant reading the health states and ranking them in order of desirability from best to worst on a 0-100 visual analogue scale (VAS) which 100 represented full health. Participants also valued a health state described as ‘dead’ to indicate whether the states were comparably worse than death.

For health states rated ‘better than dead’, participants completed the Time Trade-Off (TTO) exercise.6

For these 10 health states participants chose between: 1) to live in the health state without improvement for 10 years, or 2) to live in 10 years of full health, or 3) to indicate that the two previous options were equally desirable. For health states rated ‘worse than dead’, the ‘dead’ condition was used in which the health state was beneath 10 years of full health. Participants chose between: 1) living in full health for 10 years followed by 10 years in the health state or 2) being in full health for 20 years followed by death, or 3) to indicate that the two previous options were equally desirable.

### Statistical analysis

The distribution of the EQ-SD-SL responses were analysed and the index score was calculated using the UK TTO value set.7

The distribution of the VAS and TTO scores was analysed for each of the health states. A quality check was conducted to ensure the VAS and TTO scores were reported in the correct range (between 0-100 for VAS and 0-1 for TTO).

The diutility of AEs in relation to Base State 2 was analysed using two methods: Ordinary Least Squares (OLS) regression and Generalised Estimating Equations (GEE). The OLS regression analysis assessed the influence of each TTO AE value from Base State 2. The GEE model determined the change in utility between health states and the diutility values associated with each AE health state from Base State 2.