Value-based pricing: Getting it right for people with cancer
Prostate Cancer UK commissioned the research which is presented and discussed in this report. The report was drafted by Christina Theodore and Jacque Mallender (Matrix Evidence) supported by Peter Brazier (Blueground Partners). Prostate Cancer UK and partner charities finalised the content.

We would like to thank everyone who supported this project and contributed to the research.
Putting patients first: Why people affected by cancer should be involved in value-based pricing

NHS patients rightly expect to be among the first in the world to access the best, most innovative treatments for their condition. But as we know all too well, this is not always the case.

The shift to value-based pricing of new drugs represents an opportunity to move away from a slow and unwieldy system that focuses too much on price to one that better reflects the value medicines bring to patients, promotes innovation and gives people timely access to vital medicines based on their individual need.

Fourteen leading cancer charities are working together to help shape this change rather than simply watching it develop unchallenged. We want value-based pricing to be a dramatic improvement on the current system and one that represents what matters most to people affected by cancer. Who better to help lead on that development – with our help – than people affected by cancer themselves?

Acting on research commissioned by Prostate Cancer UK, we call on the Government to make sure people affected by cancer have an equal and active role in defining the value-based pricing process along with the Department of Health (DH) and the Association of the British Pharmaceutical Industry (ABPI).

Men and women affected by cancer have told us they want to be a part of the process. Our research shows that people affected by cancer welcome reform of a system that regularly delays access to life-extending drugs like abiraterone, relies on safety nets such as the Cancer Drug Fund in England, and results in UK-wide postcode lotteries. Their direct experience of what works (and what doesn’t) in accessing new drugs and assessing value should be integral to determining how value-based pricing will work. Let’s listen to them.

We need to make sure the voices of people affected by cancer are not ignored on value-based pricing. This report sets out key recommendations based on the findings of our research – by reading it you’ll see exactly why we think their opinions are really worth listening to.

Owen Sharp
Chief Executive
Prostate Cancer UK
Facts about cancer

• One in three people will be affected by cancer in their lifetime¹.
• In 2009 around 320,000 people were diagnosed with cancer in the UK¹.
• Survival from cancer is improving in part due to better treatments².
• There are more than 200 different kinds of cancer¹.
• Lung, breast, bowel, and prostate cancers together account for more than half of all new cancers each year¹.
• Cancer is most common in older people with three out of five cancers affecting those over 65³.
• In 2008/09 NHS expenditure on cancer services was approximately £5.1 billion⁴.

¹ Cancer Research UK. All cancers combined key facts. 2012. Available at: http://www.cancerresearchuk.org/cancer-info/cancerstats/keyfacts/Allcancerscombined/
³ Cancer Research UK. All cancers combined key facts. 2012. Available at: http://www.cancerresearchuk.org/cancer-info/cancerstats/keyfacts/Allcancerscombined/
7.0 Value

7.1 Quality of life

7.2 The value of innovation

7.3 Wider societal benefits

7.4 Other factors

8.0 Access

8.1 Equitable access to approved drugs

8.2 Equitable access to clinical drug trials

8.3 Timely process for the approval of drug treatments

9.0 Conclusion

10.0 Appendices available to view at prostatecanceruk.org/valuebasedpricing

10.1 Appendix 1: Output of literature review n/a

10.2 Appendix 2: Cancer charities discussion guide n/a

10.3 Appendix 3: Survey questions and responses n/a

10.4 Appendix 4: Programme for the deliberative event n/a

10.5 Appendix 5: Output of the deliberative event n/a

10.6 Appendix 6: Quantitative enquiries discussion guide n/a
**Key policy recommendations**

From January 2014, it is proposed that all new branded drugs will be subject to a revised process of drug pricing known as value-based pricing (VBP). Prostate Cancer UK, working in partnership with 14 other leading cancer charities, has commissioned research to ensure the views of people affected by cancer are put at the heart of the Government’s new VBP policy.

This document highlights the importance of making sure that the patient voice plays a meaningful role in both the development of VBP and the new drug appraisal process. It sets out a potential new mechanism for engaging people affected by cancer and underlines what their priorities are when assessing the value of new drugs. The need to ensure that any discussion of the wider societal benefits of new drugs does not focus exclusively on those in active employment is also highlighted.

We have a number of key policy recommendations which are set out below:

1. **Reform of the current system must lead to significant improvements in access to effective drugs.**
   Our research has found that men and women affected by cancer see the move to VBP as an opportunity to radically improve a system of pricing and assessing new drugs that currently has many failings. However, the shift must lead to an improvement in access to clinically effective drugs across the UK. People affected by cancer and the organisations that represent them will not support a system which cannot be shown to improve and promote timely and equitable access to the best possible medicines.

2. **People affected by cancer must have an equal role in the design of the VBP system.**
   The Department of Health (DH) and the Association of the British Pharmaceutical Industry (ABPI) are currently the only groups involved in deciding how new drugs should be priced and assessed in the future. Men and women affected by cancer have the experience, the knowledge and above all, the desire to help develop a better system. People affected by cancer and the organisations that represent them deserve an equal role in the design of VBP. The DH must commit to involving them in this process.

3. **A new method for involving people affected by cancer in the process of appraising individual drugs should be introduced.**
   The current processes for involving people affected by cancer in individual drug appraisals do not allow their views to be heard sufficiently. A new method is needed. Our research suggests that people affected by cancer would like to see the creation of a collective group that represents them in the assessment of individual drugs and other related issues. This group should comprise of people affected by cancer who are supported to participate fully in the appraisal process. The body should have a statutory footing and be resourced at least in part by the Department of Health. Prostate Cancer UK and its partner charities would like to work with other stakeholders to explore this further.

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4. **Drugs that improve people’s quality of life should be given the greatest value.**

Our research shows that people affected by cancer believe drugs that improve people’s quality of life should be given the greatest value. Pain relief and reduction of fatigue are seen as particularly important aspects of this. Living with constant pain or fatigue makes everyday tasks a serious challenge. Any drugs that make this even just a little bit easier are highly valued. More attention should be given to people’s overall emotional well-being rather than just looking at anxiety and depression when thinking about the value of new drugs. However, the value of drugs that can give people approaching the end of their lives precious extra time with friends and family should not be forgotten.

5. **The wider societal benefits of drugs should be carefully considered.**

To date, much of the debate around the ‘wider societal benefits’ of drugs has focused on the importance of helping people get back to work. This is an important issue but one that is not relevant to many people with cancer who are already retired, unable to re-enter the workforce or are children or young adults who are still in education or training. If the new system prioritises drugs aimed at helping people back to work, then there’s a grave risk that many people affected by cancer will lose out. It’s vital that VBP does not lose sight of the contribution that many of these people have already made to our economy and society or the role that younger people will play in the future. We also have to ensure that drugs that allow people with cancer to spend quality time with their friends and family are given the value they deserve. Nor should we forget the value of drugs that help to give hard pressed carers much needed respite and the time and space to get on with other things.

These recommendations are based on the views of people affected by cancer. However, their implementation won’t just benefit them. We believe that all men, women and children stand to gain from these recommendations, regardless of their condition, through the proposals to strengthen the voice of patients in the design of VBP and in the processes for appraising drugs across the UK. We would urge all patient organisations and charities to give their backing to our proposals.

The implementation of these proposals will need to be carefully managed. The health service in England is now in the midst of a major re-organisation. A whole range of new bodies aimed at strengthening the patient voice within the NHS are being introduced which will have major impact on the way patients are engaged. In Scotland, Wales and Northern Ireland too, there is an increased focus on involving patients in the way in which NHS services are planned and delivered. Effective collaboration with new bodies and existing methods for involving patients is crucial to the success of our recommendations.

We believe that our recommendations have an important role to play in ensuring that the new value-based pricing system genuinely reflects the needs and aspirations of the millions of people affected by cancer in the UK. We look forward to working closely with the Government, the pharmaceutical industry and other key stakeholders in the coming months to bring about a system which genuinely reflects the views of people affected by cancer and the recommendations in this report.
2.0 Executive summary

2.1 Introduction

From January 2014, it is proposed that all new branded drugs will be subject to a revised process of drug pricing known as value-based pricing (VBP)\(^6\). VBP is intended to ensure prices reflect the value a drug provides to patients and the NHS. This new process is also designed to incentivise drug companies to invest in innovative products that address unmet medical needs.

These changes represent a significant opportunity to improve problems with the current system\(^6\). We know that the NHS adopts new cancer drugs relatively slowly compared to other countries\(^7\). We also know there are variations in access to medicines across the UK\(^8\).

Furthermore, we are concerned that the Department of Health has not done enough to engage with patients and the public about these important changes.

Prostate Cancer UK (PCUK), acting in partnership with other leading cancer charities, commissioned research to ensure the views of people affected by cancer are put at the heart of the Government’s plans for VBP. The main objective of the research has been to identify what people affected by cancer value in terms of access to treatments, quality of life, how they feel about the issues around wider societal benefits of medicines and other issues relevant to the development of VBP.

The findings of this research are provided in the following report.

2.2 Background

VBP is intended to replace the Pharmaceutical Price Regulation Scheme (PPRS) for new medicines\(^9\). The PPRS is a voluntary scheme operated between the Government (represented by the Department of Health [DH]) and the pharmaceutical industry (represented by the Association of the British Pharmaceutical Industry [ABPI]) which is formally renegotiated on a regular basis. The PPRS is currently used to set drug prices by allowing companies to earn profits from branded drugs within a maximum limit.

Under VBP the price a drug company can charge will instead be determined by:

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\(^7\) Extent and causes of international variations in drug usage: a report for the Secretary of State for Health by Professor Sir Mike Richards CBE. 2010. Department of Health.
\(^9\) Drugs currently on the market which are covered by the PPRS will be dealt with through a ‘successor PPRS’ from 2014. The terms of the successor PPRS are now being negotiated by the DH and the ABPI. It is likely that the successor PPRS will operate along similar lines to the existing PPRS.
• the ‘burden of disease’: the extent to which the drug treats diseases which have the greatest physical and emotional impact on patients;
• the degree of innovation provided in terms of therapeutic benefits (over and above current treatment options) to patients; and
• the contribution to wider societal benefits – such as the benefits to carers.

Until now, there has been no formal relationship between the PPRS and appraisal bodies such as the National Institute for Health and Clinical Excellence, the Scottish Medicines Consortium or the All Wales Medicines Strategy Group. A pharmaceutical company can set a competitive price for a new drug within the rules of PPRS whilst at the same time the appraisal bodies can deem the drug to be too expensive to receive NHS funding.

Negotiations between the DH and ABPI on the arrangements of VBP started in October 2012. These negotiations will also lead with the next round of the PPRS which will continue to cover medicines that are already on the market. Prostate Cancer UK, acting in partnership with other cancer charities, wants to make sure that that the views of people affected by cancer are fully taken into account in these negotiations and that the value of treatments for people with cancer are properly considered.

2.3 Research

The research for this project was conducted across the whole of the UK over a period of 6 weeks from mid-August 2012 to the end of September 2012. A narrative review of published literature was supported by primary research which included:

• a survey of people affected by cancer;
• a deliberative event involving staff and patient representatives from cancer charities;
• qualitative enquires involving focus groups and interviews with people affected by cancer.

The research findings have been organised according to three thematic areas: patient voice, value and access.

2.4 Patient voice

The Government has not done enough to engage people affected by cancer and other patient groups in the development of value-based pricing. People of all ages affected by cancer want equal status to the pharmaceutical industry and the Government in the design of the VBP system. Charities representing people affected by cancer should have a key role in ensuring their voices are heard at each stage of the development of VBP.

Additionally, there is general consensus that the current processes for assessing the value of individual drugs do not enable the views of patients to be heard sufficiently. A new process is needed to ensure that the views of people affected by cancer can be considered in a meaningful way alongside evidence on the clinical and cost effectiveness of drugs. The people affected by cancer who contributed to our research felt that this could best be done through a new formal ‘collective’ body or group comprised of patient representatives who are provided with appropriate information and training to participate in appraisals of individual drugs. This report outlines the initial ideas suggested by the people affected by cancer who took part in this research about how this could work. The feasibility of setting up such a group should be explored further by all stakeholders.
2.5 Value

Value is a complex issue and it is unlikely that a single consensus definition can be achieved. Research participants stated that value will vary:

- between individual people affected by cancer;
- for different types of cancers;
- for different stages of the disease;
- by indication of a particular drug;
- over time and (given age, symptoms, prognosis and emotional wellbeing).

Currently there are five elements of quality of life improvements which a drug is assessed against to determine its value in relation to an individual’s relative state of health. These include considerations such as mobility, ability to independently self care, ability to participate in usual activities, level of pain or discomfort and level of anxiety or depression. These five elements will be used as part of VBP policy to assess the burden of illness for a patient and the value of therapeutic improvement delivered by a new branded drug. Research participants agreed that the definition of value should be broader and that the factors included in determining the value of a new drug should be developed in consultation with people affected by cancer.

Whilst those affected by cancer agree that the current assessment of value includes important factors which impact on quality of life, there are additional factors which should also be included such as fatigue and emotional wellbeing (this goes beyond the measures of anxiety and depression which are currently included). People affected by cancer expressed the need to achieve a positive sense of wellbeing and that low mood, lack of self-esteem/confidence and feeling stressed impacted on their ability to achieve this. The impact of a drug on the side effects of treatment and relative quality of life were also deemed equally important by research participants, who felt that returning someone as closely as possible to their previous state of emotional and physical wellbeing should be the aim of treatment.

The literature review and discussions at the deliberative event suggested that innovation is a complex concept for people affected by cancer to define for the purposes of VBP. Our research suggests that, in addition to valuing drugs that are better than existing treatments, a value should be given to:

- innovative drugs which would provide treatment for a disease where no current treatment exists;
- improvements in modes of administration;
- drugs which make a small but valuable difference to the quality of people’s lives and
- drugs which can help make people well enough to expand their treatment options in the future.

Our research suggests that people affected by cancer have significant concerns about the proposals to place a high emphasis on helping people back to work when assessing the wider societal benefits of drugs. While people affected by cancer agreed that being able to return to work is an important factor for the economy and for individuals’ emotional well-being, they are concerned about the discriminatory impacts of the proposals. It is essential to recognise that the majority of people affected by cancer are adults in the later stages of their working careers or those who have reached retirement age.\(^\text{10}\)

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\(^\text{10}\) Children and young people (those aged 0 – 24) are affected by cancer, although this is relatively rare, with around 3,600 diagnoses each year according to Cancer Research UK:

These groups of people, as well as teenagers and young children with cancer who are likely to still be in education or training, as well as those who have end of life stage cancer, would be severely disadvantaged if employment was to be included as measure of societal value. It is vital that VBP does not lose sight of the contribution that many of these people have already made to our economy and society.

When assessing the value of a drug, research participants felt that the most important measure of ‘social value’ to consider is the benefit it can have to carers and family members of the person who has cancer. Participants reported that carers can experience physical and mental health problems as a result of looking after someone with cancer. Carers have limited time to carry out their own daily living and social activities and in some cases they are unable to continue being employed as caring becomes a full time job in itself.

Additionally, our research suggests that people affected by cancer support considering end of life drugs under different criteria for defining value than other drugs.

2.6 Access

People affected by cancer want equitable access to the best possible treatments, regardless of their location, age, personal circumstances or type of cancer. Unfortunately, variation in availability of particular drugs persists leaving some people feeling they need to ‘battle’ with the NHS to challenge funding decisions. Differences in the appraisal processes across the UK for example, meant that men in England could access abiraterone, a breakthrough drug for advanced prostate cancer, on the NHS months before men in Scotland. People affected by cancer stated that VBP must promote better access to drug treatments or at the very least sustain current levels.

The Cancer Drugs Fund (CDF) has helped improve access to drugs in England which have been rejected or have yet to be approved. Our research suggests that people affected by cancer want this element of the current system to be retained. We strongly believe that provisions should be made so that if the CDF is terminated it will not lead to a reduction in the budget available for cancer drugs.

The opportunity to be involved in clinical trials is highly valued by people affected by cancer who see participation as a chance to both contribute to the evidence base and try new potentially effective treatments. However, it is apparent that although information on how to get involved in clinical trials is available, it is not getting through to people affected by cancer in a consistent manner. Accurate information regarding drug trials in the UK should be given to people affected by cancer when they discuss the treatment options available to them so the can make an informed decision about whether or not they wish to take part.

The process for assessing drugs needs to be more efficient so as not to delay the approval of certain types of drug treatments, especially those which can extend life11.

11The Medicines and Healthcare products Regulatory Agency (MHRA) has carried out a public consultation on proposals to introduce an early access to medicines scheme in the UK that will provide access to certain new medicines before they are formally licensed. The MHRA are expected to make decision on how the new scheme will be implemented in late 2012. This should be seen in the context of VBP.
2.7 Conclusions

People affected by cancer welcome reforms to the way that drugs are priced and assessed in the UK. The reforms represent a significant opportunity to improve a system that has many failings. In order to build a better system, it is vital that people affected by cancer are involved in the development of value-based pricing. The Department of Health should commit to involving them in this process. In addition, the current processes for assessing drugs across the UK do not allow the views of people affected by cancer to be heard sufficiently. Prostate Cancer UK and partner charities would like to work with other stakeholders to explore our ideas for a new method to engage patients, potentially through a new formal patient group.

Furthermore, our research showed that people affected by cancer believe drugs that improve people’s quality of life should attract the greatest value. However, this should not be valued at the expense of vital drugs that give people nearing the end of their lives precious extra time. We are also concerned that if value-based pricing prioritises drugs aimed at helping people back to work, there’s a grave risk that many people affected by cancer will lose out.

We believe that our recommendations have an important role to play in ensuring that the new value-based pricing system genuinely reflects the needs and aspirations of the millions of people affected by cancer in the UK. We look forward to working closely with the Government, the pharmaceutical industry and other key stakeholders in the coming months to bring about a system which genuinely reflects the views of people affected by cancer and the recommendations we have set out in this report.
3.0 Introduction

From January 2014, it is proposed that all new branded drugs will be subject to a revised process of drug pricing known as value-based pricing (VBP)\(^{12}\). VBP is intended to ensure prices reflect the value a drug provides to patients and the NHS. This new process is also designed to incentivise drug companies to invest in innovative products that address unmet medical needs.

Prostate Cancer UK (PCUK), acting in partnership with other cancer charities, wants to make sure that that the views of people affected by cancer are put at the heart of the Government’s plans for VBP. To this end, Matrix Evidence Ltd (Matrix) was commissioned to design and deliver a research project to find out what people affected by cancer think the most important issues are when it comes to defining the value of new drugs. The findings from the research project are detailed in this report and will be shared with the DH and the ABPI in November 2012.

The main objective of the research presented in this report is to identify what people affected by cancer value in terms of access to treatments, quality of life outcomes and other issues relevant to the development of VBP. In particular, the research has been designed to answer the following questions:

- how can VBP be made legitimate and fair in the eyes of people affected by cancer?
- how should people affected by cancer be involved in the development of value-based pricing and other debates over availability of drugs on the NHS?
- what do people affected by cancer think of the different ways in which the value of drugs can be assessed?
- what ‘quality of life’ and other factors matter most to people affected by cancer?
- what are the measures of ‘societal value’ that are important to people affected by cancer?
- do people affected by cancer think that innovation ought to be recognised, and if so, how?

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4.0 Background

4.1 Introduction

It is proposed that value-based pricing will be introduced from January 2014 and will be used to set prices for all new branded drugs. The Government’s stated objectives for VBP are that it should:

- improve outcomes for patients through better access to effective medicines;
- stimulate innovation and the development of high value treatments;
- improve the process for assessing new medicines, ensuring transparent, predictable and timely decision-making;
- include a wide assessment, alongside clinical effectiveness, of the range of factors through which medicines deliver benefits for patients and society; and
- ensure value for money and best use of NHS resources.

While the objectives of VBP were generally well-received by the organisations who responded to the Government’s initial consultation, concerns have been expressed about the lack of detail about how VBP will work in practice. Discussions to resolve these issues are underway between the Government, as represented by the Department of Health (DH), and the pharmaceutical industry as represented by The Association of the British Pharmaceutical Industry (ABPI).

4.2 The Pharmaceutical Price Regulation Scheme (PPRS)

VBP will replace the current process for drug pricing: The Pharmaceutical Price Regulation Scheme (PPRS). The PPRS is a voluntary scheme which has operated between DH and ABPI since 1957. It is used to set drug prices for branded medicines. Its purpose is to balance the need for affordable medicines whilst providing pharmaceutical companies with the financial incentives to develop innovative products. It does this by allowing companies to earn profits from branded drugs within a maximum limit. In the last agreement in 2009, a patient access scheme was created which has resulted in cost reductions being negotiated between industry and the NHS.

Within PPRS guidelines, companies are able to price products based on market conditions. However, this does not always reflect the clinical advantages a drug offers compared to existing drugs in the same area. Across the UK, three bodies already exist to provide advice about whether the price charged by a pharmaceutical company for a drug reflects its clinical value to patients and to the UK health system. They are the National Institute for Health and Clinical Excellence (NICE) in England (serving both the English and Welsh NHS), the Scottish Medicines Consortium in Scotland (SMC) and the All Wales Medicines Strategy Group in Wales (AWMSG). In Northern Ireland, once NICE has published its appraisal on a medicine, a decision is then made on whether or not to accept it.

14 Although AWMSG can carry out an independent assessment of a medicine, NICE’s assessment takes precedence.
NICE was created in 1999 to ensure the NHS gets better value for money for the drugs it buys and that they are equitably available to all patients regardless of where they live. Since January 2005, the NHS in England and Wales has been legally obliged to provide funding for medicines and treatments recommended by NICE. Up to this point there were significant variations between areas in terms of patient access to new drugs. NICE’s new mandate helped reduce this so called ‘postcode lottery’. In 2001, the Scottish Medicines Consortium (SMC) was formed to advise NHS Boards about the clinical and cost effectiveness of all new medicines.

However, despite this, variation still exists\textsuperscript{15,16} within and between nations in the UK and further action is urgently needed to address this. It is vital that all patients have access to the drugs that their doctors recommend, regardless of where they live.

NICE typically assesses the clinical value of drugs based on a consideration of cost and benefits to patients. The NICE method involves an assessment of:

- Costs: assessed by comparing of the additional cost (or saving) of providing the new treatment with that of current practice.
- Benefits: assessed with reference to the additional years of life and/or improvements in quality of life which it is proven to deliver. The measure used to measure these benefits is known as the quality adjusted life year (QALY).

When a new medicine is produced, SMC assesses it to find out:

- How effective it may be
- Which patients would benefit from it
- Whether it is more effective than treatments being used at present
- What it costs
- Whether it is worth investing NHS money to prescribe it\textsuperscript{17}.

Although there are no formal limits, NICE will generally consider drugs which cost less than £30,000 per quality adjusted life year as being cost beneficial for the NHS. A higher threshold of £50,000 per quality adjusted life year has also been introduced for higher cost drugs that extend the lives of small populations of terminally ill patients.

Until now, there has been no formal relationship between the PPRS and the NICE, SMC or AWMSG appraisal processes. A pharmaceutical company can set a price for a new drug within the rules of PPRS whilst at the same time the appraisal bodies can deem the drug to be too expensive to receive NHS funding.

\textsuperscript{16} Forgotten Conditions: misdiagnosed and unsupported, how patients are being let down. 202 Health. September 2012.
\textsuperscript{17} Scottish Medicines Consortium. FAQs. Available at: http://www.scottishmedicines.org.uk/General/FAQs#10.
4.3 Office of Fair Trading Report

In 2007 The Office of Fair Trading (OFT) reported on the future of the PPRS. It concluded that the Government should replace it “with a value-based approach to pricing, which would ensure the price of drugs reflect their clinical and therapeutic value to patients and the broader NHS.” This would align the process for setting prices for new branded medicines with the process for determining their value to patients and the UK health system.

4.4 Value-based pricing

Following the OFT’s report, the Government published proposals for a move to the value-based pricing system. The proposals will apply to drugs with new active ingredients receiving marketing approval from January 2014.

Under VBP the price a drug company can charge will be determined by:

- the extent to which the drug treats diseases which have the greatest physical and emotional impact on patients;
- the degree of innovation provided in terms of therapeutic benefits to patients; and
- the contribution to wider societal benefits – such as the benefits to carers.

This would go much further than the current methods of measuring benefits. NICE and the SMC currently only considers the effect of the drug on the patient in terms of additional years of life and/or improvement in the quality of life.

The DH has commissioned Economic Evaluation of Health and Care Interventions (EEPRU) at the University of Sheffield to research how the burden of illness could be measured and at the University of York to assess the degree of benefit a new drug needs to achieve to outweigh the current therapies. The outcomes from these two research programmes are expected in the autumn of 2012, and will inform how the new system will operate. We are concerned that this research focuses on the views of healthy people, which are likely to differ significantly to the views of people with experience of significant ill health, especially around issues of quality of life. We are also concerned that although this research will play a key role in shaping VBP policy, it is unlikely to be published for some time. This will limit the extent to which the public and patient groups can meaningfully review the research and engage in further debate.

4.5 The Cancer Drugs Fund in England

The Cancer Drugs Fund was established in England in April 2011 to provide cancer patients with access to treatments which did not receive approval under the NICE technology assessment process or have yet to be appraised. It was intended to be an interim measure until the introduction of VBP to address some of the issues in access to cancer drugs in England. The DH has stated that it wants to:

- Ensure that patients who have received drugs through the Cancer Drugs Fund and who have a continuing need for those drugs can continue to receive them.
- Determine suitable arrangements under which patients who may in the future benefit from receiving such drugs can do so, at a cost that represents value to the NHS.

However, it is not yet clear how the transition from the Cancer Drugs Fund to VBP will be managed.
4.6 Next steps

Value-based pricing is scheduled for introduction within 14 months of this report. Negotiations between the DH and ABPI which cover the arrangement for the next round of the PPRS and the introduction of VBP have already started. Yet, there are still many unknowns. We do not know the additional details defining each element of VBP and how individual drugs will be assessed. Details are also needed regarding the mechanism for implementing VBP.

It is vital that the views of people affected by cancer are taken properly into account in these negotiations. When defining value in the context of drug pricing and NHS funding, the views of patients are of paramount importance.
5.0 Research design

Four main research activities have informed the findings and recommendations outlined in this report. Figure 1 below provides an overview.

Each of the four research activities are described in more detail in this section.

5.1 Evidence review

The evidence review included a literature review and telephone interviews with key staff in partner cancer charities (N=5). The evidence review provided information about:

- the proposed approach for VBP;
- the ‘voice’ of the patient - how patients are currently or planned to be involved in the design of VBP; the selection of topics and the assessment of individual drugs;
- value – how drugs are currently and planned to be assessed e.g. quality of life; societal benefits, burden of illness, innovation; and
- access – current process and related issues.

The literature review considered:

- the policies and procedures published by Department of Health;
- evidence associated with the on-going study at the Economic Evaluation of Health and Care Interventions (EEPRU) at University of Sheffield;
- published responses from cancer community to the DH’s consultation on VBP;
- other published documents on the topic of VBP (please refer to Appendix 1 for the reference list of documents reviewed; a summary of the key extracts and the extracts with quotes from the source documents).

The telephone interviews provided a baseline of the cancer community’s current understanding of VBP and identified additional consultation and research materials produced by cancer charities for review (please refer to Appendix 2 for the questions addressed by the interviews).
The findings from the evidence review were used to shape the focus of the survey and deliberative event. This ensured that the primary research activities were designed to further develop an understanding of VBP from the perspective of the cancer community and people affected by cancer.

5.2 Survey
An opinion survey was developed to gather responses from people affected by cancer on the following topic areas:

- **drug treatments:**
  - whether respondents were receiving the drugs recommended by their doctor and if the drugs were available when needed;
  - whether respondents felt fully informed about the drug treatment choices they faced;
  - whether respondents understood the pros and cons of the different drug treatment choices they faced; and
  - the impact of their drug treatment on quality and extension of life.

- **determining the value of new drugs:**
  - the benefits which should be given the highest priority when assessing the value of a new drug;
  - the factors that should be given the highest priority in deciding the price of a new drug; and
  - how the process for deciding the value of new drugs in the UK should work.

The survey asked respondents to select statements which applied to them or rank statements in accordance with their level of agreement or order of priority. The responses from the survey were analysed using descriptive statistics (percentages and frequencies) for the whole sample and by subgroups of respondents (please refer to Appendix 3 for the full survey questions and responses).

The survey was launched online on 29th August 2012 and ran for a period of 4.5 weeks. A total of 412 respondents participated. The survey collected a range of demographic and relevant background information on participants. Section 5.5 summarises the main characteristics of the sample.

5.3 Deliberative event
A half-day deliberative event took place on September 3rd 2012 at the Kings Fund and was attended by chief executives, staff and patient representatives from 22 cancer charities. The deliberative event was designed to:

- gain insight into definitions of ‘value’;
- contribute to a greater understanding of the objectives of VBP;
- work towards a consensus on main policy issues.

The event included a range of guest speakers who presented on the topic areas of ‘the patient voice’, ‘value’ and ‘access’ to set the context for round table discussions on specific elements of value-based pricing. The round table discussions addressed the following questions:
• what is the role and participation of groups representing people affected by cancer in defining the new pricing system?
• how should patient groups and charities best participate in value and reimbursement pricing decisions for individual products to be assessed under the new pricing system?
• what features must be present in the VBP process to ensure people affected by cancer are able to access the drugs they need?
• what aspects of value do people affected by cancer think are important to consider when pricing and assessing medicines?

(Please refer to Appendix 4 for the event programme and Appendix 5 for the output of the event).

5.4 Qualitative enquiries
Qualitative enquiries were undertaken with people affected by cancer to capture their views about:

• the quality of life factors which should be taken into consideration when assessing the value of a drug;
• the potential benefits to society which should be taken into consideration when assessing the value of a drug;
• how people with cancer should be involved in decisions regarding VBP, the assessment of new drugs and what support and information they require to effectively participate in these decisions; and
• how people with cancer should be involved in decisions regarding their own drug choices and what support and information they require to effectively participate in these decisions.

(Please refer to Appendix 6 for questions addressed by the qualitative enquiries).

The qualitative enquiries took the form of telephone interviews and four focus groups located in London, Leeds, Cardiff and Glasgow.

In advance of the interviews/focus groups, participants were provided with information regarding:

• the context of the research;
• the nature of the topics to be discussed;
• time commitment required;
• how the information they provided will be used to inform the research; and
• issues pertaining to confidentiality, voluntary participation and their right to withdraw from the research activity.

Researchers obtained verbal consent from those participating in telephone interviews and written consent from those who attended the focus groups.

The information collected by the qualitative and quantitative enquiries was thematically analysed. The main component of this approach is the ‘thematic framework’, which categorises, organises and presents the data under key themes (i.e. patient voice, value, and access). Once themes were identified, the views of participants were summarised into the framework to allow comparisons between the outcome of the interviews and each focus group.

A total of 31 people affected by cancer participated in the qualitative enquiries. Section 5.5 summarises the main characteristics of the sample.
5.5 Recruitment and sample

Prostate Cancer UK recruited participants for the survey and the qualitative enquiries using the following methods:

- asked members of the Cancer Campaigning Group and Cancer 52 to publicise the research among their networks;
- sent the details of the research activities to PCUK’s volunteer network (approximately 1,200 people) and campaign supporters (approximately 800 people);
- advertised the research activities on the home page of PCUK’s website and had a dedicated web page on the project to provide further information;
- tweeted information - with over 100 retweets from other charities, organisations, and politicians;
- posted information on Facebook about the research (reaching over 6000 people, with almost 300 engaged users); and
- placed ‘Letters to the Editor’ about the survey to regional titles across the UK.

The mean age of survey respondents was 54. The mean age of those who participated in the qualitative enquiries was 61. There were slightly more males (51.9%) than females (47.8%) who responded to the survey, however there was a much larger proportion of males (77.4%) than females (22.6%) who participated in the qualitative enquiries. The majority of survey respondents and those who participated in the qualitative enquiries currently have cancer (36.6% and 54.8%). Just under a quarter of survey respondents and over half of those who participated in focus groups said they either had or have had stage 4 cancer (22.1% and 59% respectively). However, it is important to note that 32.4% of survey respondents indicated their stage of cancer as ‘other’.

Both the survey and qualitative enquiries collected data on participant’s background information. The table below summarises the main characteristics of these participants (please see Appendix 3 for further information).
**Table 1: Research Participants**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Category</th>
<th>Survey respondents (%)</th>
<th>Qualitative enquiries participants (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Male</td>
<td>51.9 (n=214)</td>
<td>77.4 (n=24)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>47.8 (n=197)</td>
<td>22.6 (n=7)</td>
</tr>
<tr>
<td></td>
<td>Transgender</td>
<td>0.2 (n=1)</td>
<td>0</td>
</tr>
<tr>
<td>Area of residence</td>
<td>Scotland</td>
<td>8.8 (n=36)</td>
<td>22.5 (n=7)</td>
</tr>
<tr>
<td></td>
<td>Wales</td>
<td>3.9 (n=16)</td>
<td>6.4 (n=2)</td>
</tr>
<tr>
<td></td>
<td>Northern Ireland</td>
<td>1.2 (n=5)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>England</td>
<td>86.1 (n=352)</td>
<td>71 (n=22)</td>
</tr>
<tr>
<td>Dependants</td>
<td>Yes</td>
<td>44.7 (n=184)</td>
<td>51.6 (n=16)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>55.3 (n=228)</td>
<td>48.4 (n=15)</td>
</tr>
<tr>
<td>Affected by cancer**</td>
<td>Has cancer now</td>
<td>36.6 (n=144)</td>
<td>54.8 (n=17)</td>
</tr>
<tr>
<td></td>
<td>Has had cancer in the past but there is no sign of the cancer</td>
<td>29.0 (n=114)</td>
<td>38.7 (n=12)</td>
</tr>
<tr>
<td></td>
<td>Has a direct family member with cancer</td>
<td>34.1 (n=134)</td>
<td>9.6 (n=3)</td>
</tr>
<tr>
<td></td>
<td>Cares for someone with cancer</td>
<td>7.4 (n=29)</td>
<td>0</td>
</tr>
<tr>
<td>Stage of cancer</td>
<td>Stage 1**</td>
<td>19.0 (n=48)</td>
<td>11.7 (n=2)</td>
</tr>
<tr>
<td></td>
<td>Stage 2**</td>
<td>11.1 (n=28)</td>
<td>11.7 (n=2)</td>
</tr>
<tr>
<td></td>
<td>Stage 3**</td>
<td>8.7 (n=22)</td>
<td>5.9 (n=1)</td>
</tr>
<tr>
<td></td>
<td>Stage 4**</td>
<td>22.1 (n=56)</td>
<td>59 (n=10)</td>
</tr>
<tr>
<td></td>
<td>Don’t know</td>
<td>6.7 (n=17)</td>
<td>11.7 (n=2)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>32.4 (n=82)</td>
<td>0</td>
</tr>
<tr>
<td>Type of cancer**</td>
<td>Bowel Cancer</td>
<td>7.2 (n=18)</td>
<td>11.8 (n=2)</td>
</tr>
<tr>
<td></td>
<td>Breast Cancer</td>
<td>20.4 (n=51)</td>
<td>11.8 (n=2)</td>
</tr>
<tr>
<td></td>
<td>Prostate Cancer</td>
<td>53.2 (n=133)</td>
<td>82.3 (n=14)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>25.6 (n=64)</td>
<td>29.5 (n=5)</td>
</tr>
<tr>
<td></td>
<td>Don’t know</td>
<td>0.8 (n=2)</td>
<td>0</td>
</tr>
</tbody>
</table>

*Note that a respondent can be affected by cancer in more than one way and therefore the total percentage will not add up to 100 or the total sample size.

**Note that a respondent can have more than one type of cancer therefore the total percentage will not add up to 100.

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18 The cancer is relatively small and contained within the part of the body it started
19 The cancer has not started to spread into surrounding tissue, but the tumour is larger than stage 1
20 The cancer is larger and has started to spread into the surrounding tissues and there are cancer cells in the lymph nodes in the area
21 The cancer has spread from where it started to another part of the body (secondary or metastatic cancer)
6.0 Patient voice

6.1 Design of VBP

The Government has not done enough to engage people affected by cancer and other patient groups in the development of value-based pricing. People affected by cancer want equal status to the pharmaceutical industry (ABPI) and the Government (DH) in the design of the VBP system.

Participants in the deliberative event and the qualitative enquiries consistently reported that people affected by cancer should have equal status to the pharmaceutical industry (ABPI) and the Government (DH) in the design of the VBP system. They wanted people affected by cancer to participate in policy discussions on an equal footing. The ‘patient voice’ should be represented in all aspects of the debate on VBP including the design of the VBP process and how individual drugs will be appraised.

This level of involvement would require people affected by cancer to be better informed about the VBP proposals and current system for appraising drugs. Participants support charities having a mandate to support the process of patient engagement.

Survey respondents supported the findings from the deliberative event and qualitative enquiries. There was positive support for the following statements:

- cancer charities, or other patient representative groups, should be consulted about the rules used to determine the value of new cancer drugs (95%);
- those affected by cancer should be consulted about the rules used to determine the value of new cancer drugs (86%).

It was also felt that some charities, especially smaller ones, may require greater support to put the patient voice forwards in a meaningful way. All participants who contributed to the qualitative enquiries and the deliberative event felt that a single collective voice representing people affected by cancer would carry significantly more influence and weight than individual representations.

6.2 Appraisal of individual drugs

The current processes for assessing the value of individual drugs do not enable people affected by cancer to be heard sufficiently. A new process is required which enshrines the need for patient contributions to be listened to:

‘Don’t ask for us [people affected by cancer] to be involved and then fail to listen to what we have to say.’

It was noted that in the process of drug approval, anecdotal evidence from a single person affected by cancer does not carry the same amount of weight as clinical effectiveness evidence. One participant who attended a NICE appraisal committee meeting said:

‘I expressed my opinion and felt I was there so they [NICE] could say [I’ve] been on the panel and then that voice is completely ignored.’
Participants felt that there is a need to present qualitative evidence from the perspective and experiences of those affected by cancer in an impactful way.

Survey respondents supported the findings from the deliberative event and qualitative enquiries. There was positive support for the following statement:

- those affected by cancer should be directly consulted about the value of each new cancer drug (72%).

The majority of participants who contributed to the qualitative enquiries felt that the patient voice could be best represented through a formal ‘collective’ body or group to which patient representatives are then selected and provided with appropriate information and training.

### 6.3 How this could work

The recommendations set out in this section are initial ideas for how a new patient group could operate, which were gathered from the people affected by cancer who took part in this research project. We hope they will be a starting point for discussions about how this group could work. The detail of how to implement these proposals will need to be carefully discussed by the charities supporting this report and other relevant stakeholders.

The majority of participants who contributed to the qualitative enquiries felt that a ‘collective’ representation of those affected by cancer should be underpinned by the following characteristics and principles:

- people affected by cancer should be represented as a ‘single’ voice;
- representatives could be selected from existing networks from each cancer charity;
- leadership of the body/group is likely to be a full time role(s) and therefore should be paid employment. This could be funded jointly by cancer charities;
- the cancer charities could support the representatives by providing information on:
  - ‘hot’ topics being debated at a policy level with regards to the development of new drugs;
  - relevant research;
  - information on drugs which are being developed and appraised;
  - the appraisal process for individual drugs;
  - clinical information, so representatives can understand clinical effectiveness data and contribute to and/or challenge discussions in this area at panel meetings; and
  - softer skills such as negotiation, communication, influencing and managing the ‘politics’ of such meetings. These were seen as essential skills to be equipped with if representatives are to have a strong voice and influence decisions.
- a process needs to be agreed for supporting patient representatives, potentially through a full-time secretariat.
- the group could be involved in varying levels of engagement:
  - at a strategic/policy level the collective voice of those affected by cancer could be put forwards by the body/organisation – ‘collective representation’;
  - at NICE and SMC boards the representatives who are part of the body/group could attend the panel meetings;
- to ensure that the views of people affected by cancer have as strong a representation as clinical experts and health economists the group could engage in a wider consultation through charities’ existing networks. It was felt that this will then add more weight in terms of decision making;
• the use of sub-groups on particular topics could be explored to ensure relevant representatives are put forward for specific appraisals;
• the system should be transparent and open and people representing others should be required to report back to the wider community.

We believe that a new method for involving people affected by cancer in the processes of drug appraisals across the UK is needed. The principles identified in our research, as set out above, form a useful starting point for Prostate Cancer UK, our supporting charities, the Department of Health, NICE, the SMC and other relevant stakeholders to discuss the feasibility of creating a new formal group to represent patients in this way. We look forward to working towards the implementation of these proposals. We will also seek to collaborate with the new bodies for patient engagement in England such as Healthwatch and Health and Well-Being Boards.

6.4 Individual decisions about treatment
The research also explored the views of people affected by cancer at the point of treatment. The survey findings indicate that those currently receiving drug treatment for cancer (46%) felt fully informed about and understood the pros and cons of their drug treatment (78% and 75% respectively). However, when this issue was discussed in detail at the deliberative event and during the qualitative enquiries, participants felt there was a need for more information about drug treatment options, availability, side effects and clinical trials to be proactively provided through a ‘single point’ of contact. Sources of information about drug treatments were suggested, including: health professionals (consultants; nurses, pharmacists); drug manufacturers; the internet; cancer charities; and other people affected by cancer. For one participant, asking other people affected by cancer had been the main way they found out how best to cope with the side effects of chemotherapy. Another participant spoke of being given a short time to live and choosing to do their own research:

‘I was given 18 months to live and my oncologist didn’t want to know... I did my own research and went to X [doctor] and I’m still here.’

Participants said they wanted more information about drug treatments, options, side effects and clinical trials. Although this information exists, this and other research, such as the National Cancer Patient Experience Survey, suggest it is not being consistently disseminated to people affected by cancer. Amongst health professionals, GPs need to be particularly targeted to improve information and signposting for people affected by cancer to obtain further information on these issues.

All participants who contributed to the qualitative enquiries felt that more could be done to inform people affected by cancer of the side effects and effectiveness of particular drugs. Some participants felt they were not given enough information. Participants stated that if an individual knows what to expect they can prepare for it. It was suggested that those who have been better informed about the side effects of their drug treatment felt that they could deal with the outcome more effectively than if they had limited knowledge. It is vital that all people affected by cancer are given full information on side effects prior to the start of drug treatment. This should include alternative treatment options with less severe side effects and their associated advantages and disadvantages.

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7.0 Value

Value is a complex issue for people affected by cancer. Participants stated that value will vary:

- between individual people affected by cancer;
- for different types of cancers;
- for different stages of the disease;
- by indication of a particular drug;
- over time and (given age, symptoms, prognosis and emotional wellbeing).

However, our research does suggest that people affected by cancer support a broadening of the definition of ‘value’ when it comes to assessing medicines.

Three dimensions of value were considered in the research:

1. The value of improvements to the quality of life of an individual affected by cancer;
2. The value of innovation;
3. Value to the wider society.

Each is explored further in the following paragraphs:

7.1 Quality of life

Currently there are five elements of ‘quality of life improvements’ a drug is assessed against to determine its value in relation to an individual’s relative state of health:

- Level of mobility;
- Ability to independently self-care;
- Ability to engage effectively in usual activities;
- Level of pain/discomfort; and
- Level of anxiety/depression.

These elements will be used as part of VBP policy to assess the burden of illness for a person and the value of therapeutic improvement delivered by a new branded drug.

Our research indicates that people affected by cancer agree with the inclusion of the five elements listed above in any assessment of the value of improvements a drug makes to quality of life. Survey respondents indicated that priority should be given to the ability of a drug to improve quality of life (99%) and extend life (98%). All five of the current elements used to measure quality of life were rated as being of high or medium priority for people with cancer:

- pain/discomfort (99%);
- physical mobility (97%);
- daily living activities (independent living - 97%) and
- anxiety and depression (improved mental health - 96% and stress relief - 96%).

The highest priority was given to pain relief.
The majority of participants in the qualitative enquiries found it difficult to put the five quality of life factors into a hierarchy but noted that, if they had to, the relief of pain would be the highest priority. One participant stated:

‘Pain is probably the most important because it impacts on all the other quality of life measures...but we know even with pain, that this can be exacerbated by anxiety and depression which may make it work and vice versa.’

All participants in the qualitative enquiries felt that there are additional factors which should be included in the assessment of the impact of a drug on quality of life.

- **Side Effects:** Participants who contributed to the qualitative enquiries stated that they would like more emphasis to be placed on the side effects of drugs when assessing the impact of a drug on the quality of life. One participant stated that:

  ‘The cumulative effect of many mild/moderate side effects from one drug is much greater than each individual problem.’

- **Fatigue:** The majority of participants which contributed to the qualitative enquiries stressed that fatigue was a major factor which should be considered, one participant stated:

  ‘What would have improved my quality of life would have been being able to have the energy to do something other than receive chemotherapy every day.’

- **Emotional Wellbeing:** Anxiety and depression are currently included as elements of value in the measurement of quality of life. However, participants in the qualitative enquiry perceived this as too narrow a definition; this element should encompass the domain of ‘emotional wellbeing’ as a whole or emotional wellbeing should be included as a separate element. One participant stated:

  ‘Your well-being, how happy you are...it’s just as important as the physical ones.’

  Related to emotional well-being was the ability to control ‘mood’. This was considered an important factor given that drugs can induce mood swings and this can impact on an individual’s quality of life.

Survey respondents also considered the ability of a drug to limit side effects (98%) and to improve physical energy (96%) to be important factors when considering the value of a drug.

The majority of participants felt that relative quality of life benefits of drug treatment were very much age dependent and also dependent on the stage of a person’s cancer. Someone with palliative care needs will be interested in different things to someone who is potentially seeking more years of life. Similarly, young people are likely to have different views to older people. Finally, there was consensus among participants that quality of life benefits were equally important to the clinical effectiveness of a drug and most important when comparing one drug with another in terms of choice of treatment.
The additional elements reported by the survey as being important to quality of life and which are not currently assessed are:

- quality of time with family (98%);  
- personal dignity (96%); and  
- ability to care for dependents (87%).

Other factors were rated as less important, including: more free time (72%); financial savings (54%) and an active sex life (54%).

7.2 The value of innovation

Our research suggests that, in addition to valuing drugs that are better than existing treatments, a value should be given to:

- innovative drugs which would provide treatment for a disease where no current treatment exists;  
- improvements in modes of administration;  
- drugs which make a small but valuable difference to the quality of people’s lives and  
- drugs which can help make people well enough to expand their treatment options in the future.

Responses to the survey suggested that, in considering value, priority should be given to drugs which would provide treatment to people affected by cancer for whom know existing treatment is available (97%).

The research identified improvements in the method of drug administration as a specific aspect of innovation which is important to people affected by cancer but is not covered in the current measures of quality of life improvements. Research participants felt that there is a need to place a greater emphasis on the development of drugs which can be administered in different ways and in different settings.

The research indicates that being able to receive treatment at home is of particular importance to those affected by cancer. This was considered more important than any other change in method of delivering drug treatment. Participants spoke of the need to decrease the number of visits to hospital or at least the frequency at which this has to occur. Participants explained that going into a hospital setting has a negative impact on their emotional well-being as it can be very exhausting and remind them they have cancer. Furthermore, hospital visits were reported as costly in terms of the cost of travel and need to take time off of work. Participants spoke about being completely reliant on others to take them to hospital for drug treatments as they were too unwell to use public transport or drive themselves. One participant stated:

‘If I had been on my own, I probably wouldn’t have been able to finish my treatment.’

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23 CLIC Sargent has also done research which highlights the importance of providing clinical care at and closer to home for children and young people with cancer who receive treatment often many miles from home for up to a period of three years. For further details, please see CLIC Sargent’s More Than My Illness reports which can be accessed online at http://www.clicsargent.org.uk/content/more-my-illness.
Overall, a drug treatment which provides this type of benefit was seen by participants as critical to improving the quality of life and should be considered even though it may not necessarily provide any added clinical benefit such as additional life years. This was felt to be an important issue which needs to be recognised and accounted for in the new pricing system.

Survey respondents also gave priority to whether the drug replaces more intensive treatments, such as surgery, or treatments that can only be given in hospital, such as radiotherapy (96%).

### 7.3 Wider societal benefits

The participants who contributed to the qualitative enquiries felt that the most important measure of 'social value' was the benefit a drug can have to carers and family members of the person who has cancer. Participants reported that carers can suffer physical and mental health problems as a result of looking after someone with cancer. They have limited time to carry out their own daily living and social activities and in some cases they are unable to continue being employed as caring becomes a full time job in itself. One participant stated:

> 'My husband had to use every single day of his annual leave looking after me and taking me to the hospital. He also had to take unpaid leave in addition...it was hugely stressful for him as well as exhausting trying to juggle work commitments with caring for me.'

These findings were mirrored by the survey responses. Survey respondents were asked to assign priority to benefits for those caring for people with cancer. Reduction in stress relief for carers, and carers having more free time, were each rated as high or medium priority (97% and 90% of respondents respectively) with financial savings for carers given a high or medium priority rating by 69% of respondents.

The ability of a person with cancer to work, pay their taxes and financially look after their dependents was also considered an important wider societal benefit by participants in the qualitative enquiries. One person stated:

> 'There are not unlimited funds and the population is getting older.'

They highlighted the importance of employment to them in terms of their own emotional well-being. For example, returning to work (paid or voluntary) would provide structure to their day, take their mind off the cancer, provide an opportunity for them to engage with a range of people, enable them to achieve some of their goals and aspirations and improve their self-esteem / confidence.

However, concerns were raised about the possible consequences of including returning people to employment as a societal benefit as it could potentially disadvantage many people affected by cancer. Though participants agreed that being able to return to work is an important factor to the economy, it is essential to recognise that the majority of people affected by cancer are adults in the later stages of their working careers and those who have reached retirement age. Therefore, these individuals have already significantly contributed to the economy throughout their adult lives. Similarly, those who have end of life stage cancer as well as children and young people, who are likely to still be in education or training would be severely disadvantaged if employment was to be included as measure of societal value.
Many participants spoke about the importance of drugs which give people who are reaching the end of their lives precious extra time. It was also felt that end of life drugs should be considered under different criteria for defining value to ensure their importance to people affected by cancer is highlighted. For example, these drugs should include less weighting on societal value as the person will not be able to resume normal daily living activities such as paid employment.

There were mixed views about giving priority to drugs which treat conditions in certain groups such as children who would have longer to live and therefore be able to make more significant future contributions to society. Doing so would disadvantage those of retirement age who have already spent their working life in paid employment or may be carrying out voluntary work to help with their local communities. One participant stated:

'We don't value older people in society and anything that weights employment above other things would be discriminatory.'

The majority of participants felt that there should be no differentiation with regards to developing drugs for different age groups. One participant stated:

'Every life is exceptional.... every life is a life that is valuable.'

Another participant added:

'We need to value all life regardless of age, race, gender etc. – that has to be the essence of humanity.'

7.4 Other factors

The survey specifically asked respondents about other factors that should be considered when assessing the value of a drug treatment. Sixty-one per cent of survey respondents stated that the cost of developing new drugs should be taken into consideration (28% giving this a high priority rating), and 44% stated that priority should be given to drugs which save money for the tax payer (14% giving this a high priority rating). Meanwhile, 37% stated that priority should be given to the value of the pharmaceutical companies’ contribution to the UK economy (11% giving this a high priority rating). Finally, 14% of survey respondents stated that dividends and profits should be taken into consideration (4% giving this a high priority rating) and 59% felt that this should not be considered at all.

Overall, the survey responses indicate that the assessment of a drug should not be valued on the profits or dividends for shareholders. However, respondents acknowledged that some priority should given with regards to cost of developing the drug and the savings it will bring to tax payers and value it generates for the economy.
8.0 Access

People affected by cancer want equitable access to the best possible treatments, regardless of their location, age, personal circumstances or type of cancer. Our research indicates there is a need for more equitable access to approved drugs and clinical drug trials across the UK. It also found that people affected by cancer want the processes for assessing drug treatments to be made more efficient so as not to delay the approval of certain types of drug treatments, particularly those which can extend life. These are discussed in more detail below.

8.1 Equitable access to approved drugs

All participants who contributed to the qualitative enquiries and the deliberative event stated that there needs to be equitable access to drug treatments regardless of where people affected by cancer live in the UK. It was reported that at present there is considerable variation within Scotland and across England in terms of which approved drugs are being funded by NHS commissioners. One participant stated:

'[Drug treatments] should all be [available] at a national level so if it's available for one [person] it should be available for everybody.'

The process required to challenge funding decisions was reported as ‘difficult’ and ‘stressful’ with one participant stating:

'I spent days and days filling in forms...patients should not have to fight bureaucracy as well as the cancer.'

Some participants were unable to obtain the drug treatment of their choice through the NHS and had to turn to their private health care insurance or personal financial resources. An outcome of this for one participant was improved quality and extension of life beyond their original prognosis. These participants reported that some health care insurers are funding drug treatments that the NHS either won’t fund or are licensed but not approved for prescribing.

Other participants had turned to the Cancer Drug Fund (in England) to seek funding of a drug which was not available from their local NHS health commissioners. The Cancer Drugs Fund is viewed as a ‘safety net’ and participants felt that its value should be reinforced and that this element of the existing system should be retained. Some participants were concerned that VBP would abolish this funding stream and worsen the current issues experienced by people affected by cancer in obtaining funding for the drug treatment of their choice. People affected by cancer stated that VBP must promote better access to drug treatments or at the very least sustain current levels. Provisions should be made so that if the CDF is terminated it will not lead to a reduction in the budget available for cancer drugs.

Participants who contributed to the qualitative enquiries and deliberative event stated that VBP must be designed to minimise the ‘post code lottery’ with regards to access to drug treatments. It was suggested that this requires the development of UK wide commissioning criteria to support this.
Of those survey respondents who are currently receiving drug treatments (46%), 98% are currently receiving the drug treatment recommended by their doctor and 99% stated that their drugs are available when they have needed them. However, it is important to note that doctors are likely to recommend drug treatments which are currently funded by their local health commissioners and therefore readily accessible.

Overall, people affected by cancer think it is vital that VBP leads to improved access to drugs.

### 8.2 Equitable access to clinical drug trials

Participants in the qualitative enquiries and deliberative event mentioned that they would value the opportunity to be involved in clinical drug trials so they can contribute to the evidence base and have the opportunity to try a new drug which might provide effective treatment. However, it is apparent that although information on how to get involved in clinical trials is available, it is not getting through to people affected by cancer in a consistent manner. Our research suggests that people affected by cancer want more information about clinical trials. One participant stated that:

‘When I was ill I was always interested in [clinical drug trials] but no-one seemed to know anything about them and there was no information to hand.’

Another participant added:

‘If you’re under a hospital that doesn’t do [drug] trials they won’t tell you anything. [The hospital] won’t even admit that trials go off [take place].’

Overall, there was agreement that everyone with cancer should be directed by their doctors to information about clinical drug trials in the UK and become a participant if they meet the inclusion criteria. It should not just be offered to those in the vicinity or locality where the drug trial is running.

The findings from the research regarding information on clinical drug trials resonate with that of the National Cancer Patient Experience Survey (NCPES) 2011-12. The findings from the NCPES showed that:

- only a third (33%) of patients said that taking part in clinical research had been discussed with them;
- a high proportion (95%) of those patients who had research discussed with them said that they were glad to have been asked and welcomed the opportunity;
- just over half (53%) of those who were not spoken to about taking part in research would like to have been asked.
8.3 Timely process for the approval of drug treatments

Several participants who contributed to the deliberative event and qualitative enquiries spoke of the need to speed up the process for the approval of drug treatment which they felt was too lengthy, particularly for drugs that extended life. One participant stated:

‘You’re waiting for longer term evidence; in the meantime, people are dying.’

Participants provided suggestions for how the process for the approval of drug treatments could be made more efficient:

- where UK data is limited we should use international data to inform decisions regarding the approval of drugs;
- a streamlined system needs to be in place to ‘fast track’ the assessment of particular drugs;
- less rigorous long term impact assessments must be introduced for end of life drugs;
- access to cancer drugs should be fast-tracked once cost-effectiveness has been proven.

Participants felt that life extending drugs should be fast tracked through the approval process. The research indicates that people affected by cancer would support the early access Medicines and Healthcare products Regulatory Agency (MHRA) scheme.
9.0  Conclusion

People affected by cancer welcome reforms to the way that drugs are priced and assessed in the UK. The reforms represent a significant opportunity to improve a system that has many failings. In order to build a better system, it is vital that people affected by cancer are involved in the development of value-based pricing. The Department of Health should commit to involving them in this process. In addition, the current processes for assessing drugs across the UK do not allow the views of people affected by cancer to be heard sufficiently. Prostate Cancer UK and partner charities would like to work with other stakeholders to explore our ideas for a new method to engage patients, potentially through a new formal patient group.

Furthermore, our research showed that people affected by cancer believe drugs that improve people’s quality of life should attract the greatest value. However, this should not be valued at the expense of vital drugs that give people nearing the end of their lives precious extra time. We are also concerned that if value-based pricing prioritises drugs aimed at helping people back to work, there’s a grave risk that many people affected by cancer will lose out.

We believe that our recommendations have an important role to play in ensuring that the new value-based pricing system genuinely reflects the needs and aspirations of the millions of people affected by cancer in the UK. We look forward to working closely with the Government, the pharmaceutical industry and other key stakeholders in the coming months to bring about a system which genuinely reflects the views of people affected by cancer and the recommendations we have set out in this report.
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*Calls are recorded for training purposes only.
Confidentiality is maintained between callers and Prostate Cancer UK.

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