

## **Cancer52 Response to Investing in Specialised Services**

### **1 Do you have any comments on the principles that we have proposed to underpin the process for making investment decisions about specialised services?**

Cancer52 represents 80 predominantly small cancer charities united by their vision of seeing a better future for everyone affected by rare and less common cancers. Given our membership, we are particularly concerned about ensuring that those with rare and less common cancers are not left behind.

Cancer52 has a number of concerns about both the clarity and practice relating to the principles that NHSE has proposed.

Cancer52 calls for:

- Clarity in what hierarchy will be used across the principles. For example: will principle ii) a) there is adequate and clinically reliable evidence to demonstrate effectiveness 'trump' principle iii) a) may accord priority to treatments or interventions for rare conditions even where there is limited published evidence on clinical effectiveness, recognising that the rarity of the condition may make such data unavailable
- Inequalities remains a concern for many patient organisations, particularly given evidence of ageism in cancer (see Lawler et al Ageism in cancer care, *BMJ* 2014;348:g1614) and the need to tackle the disparity that those with rare and less common cancers account for more than half of cancer deaths. We know from an analysis carried out for Cancer52 of the findings of the National Cancer Patient Experience Survey that rare and less common cancer patients have less satisfactory NHS experiences than other cancer patients. There are differences on nearly every measure.
- There are also inequalities that relate to variations in survival, specifically for those cancers with extremely low survival rates. How will NHSE measure inequalities, included in principle iii) c), and the impact of investment/dis-investment decisions on them?
- Social impact is an area that has been subject to much debate as illustrated by the rejected proposals for Value Based Assessment (VBA). We call for NHSE to clarify how social impact will be measured, referred to in principle iii) d)?

We also want companies to ensure that they share data as early as they are able to with NHSE. NHSE should not discount data that is not yet published, as long as they can be assured about how it is generated and the company is in the process of publishing the data. Similarly NHSE should be proactive in seeking out data to inform decisions, such as for techniques including radiotherapy and ablation.

Cancer52 is concerned that NHSE will not necessarily meet the proposed principles in practice. Our view is that NHSE needs to become the organisation that it aspires to in setting out these principles. NHSE faces a credibility problem; NHSE has not, to date, demonstrated that it can meet the general principles as to prioritisation that it has set out.

- NHSE has not yet demonstrated sufficient transparency and openness in the way that it conducts business. For example, we know from the meeting notes of the Patient and Public Voice Assurance Group (available at: <http://www.england.nhs.uk/commissioning/spec-services/get-involved/ppv-ag/>) that many patient groups are concerned about NHSE's openness and transparency. We also know from a response to a Freedom of Information Request from NHSE in November 2014 that there are no plans to publish meeting minutes from the Clinical Priorities Advisory Group (CPAG) until the 2015/16 financial year. This means that there are no meeting minutes from this group open to scrutiny since NHSE was set up
- NHSE has not demonstrated that it has taken into account all relevant guidance. For example, the 'interim' generic commissioning policies (having been interim now for two years and to date, NHSE has not published updated policies despite intentions to do so in October 2013 and during summer in 2014) do not always include statutory duties that we believe are relevant. The policy on experimental and unproven treatments (available at: <http://www.england.nhs.uk/wp-content/uploads/2013/04/cp-06.pdf>) does not include any reference to the duty under the Health and Social Care Act 2012 for NHSE to promote research in the NHS (para 13L available at: <http://www.legislation.gov.uk/ukpga/2012/7/part/1/crossheading/further-provision-about-the-board/enacted>)

We accept that NHSE must work within the broader policy framework and politics of the day for the NHS; these, in large part, determine the affordability envelope within which the NHSE must work. This can, at times, cause tension between delivering cost effective treatments and what is affordable, just as we've seen with the example of Sofosbuvir for treating chronic hepatitis C with positive guidance delayed (see <https://www.nice.org.uk/guidance/ta330/chapter/5-implementation>), driven by affordability concerns according to Chief Executive of the Hepatitis C Trust (see <http://www.hepctrust.org.uk/hepatitis-c-drug-sofosbuvir-delayed-nhs-due-high-cost>).

Cancer52 welcomes commitments from some of the political parties to funding the NHS in line with the needs identified by Simon Stevens. We hope that political statements will turn into commitments in the Comprehensive Spending Review that we anticipate following the General Election.

## **2 Are there any other principles that you think NHS England should adopt as part of its process for making investment decisions about specialised services?**

Based on the public consultation we cannot see appeal as part of the decision making process. We believe that appeal is an important part of a 'reasonable' process and ask NHSE to clarify the opportunities and rules for appealing decisions relating to investing in specialised services - particularly in relation to the opportunities for patients and patient organisations to appeal.

This builds on the current debate about the opportunities and role for patient groups in appealing decisions under the CDF, as illustrated by debate in the House of Lords on the 16<sup>th</sup> March 2015 (available at: <http://www.publications.parliament.uk/pa/ld201415/ldhansrd/text/150316-0001.htm#1503166000477>). Earl Howe states that: "NHS England believes that any patient group or third party not involved intimately with that due process would not be in a position to make a judgment about whether the process had been followed correctly." We would agree: we want patient organisations to have both the involvement that Earl Howe speaks to, and then they would indeed be in a position to know that the process has been followed correctly. And so it follows that they should then be able to appeal.

We also note that alignment with other key initiatives should feature more clearly in the intentions of NHSE. For example, the new Strategy for Cancer, the Innovative Medicines and MedTech Review, the results of the work of the CDF Working Party, and the Spending Review following the Election as well as the development of co-commissioning. NHSE should also make it clear the consequences and implications arising out of the current complexities of running two different National Tariffs and gain share arrangements. Put simply, NHSE needs to set out clearly what all of this means to patients and the services that they will be receiving under the banner specialised commissioning in the future.

### **3 Do you have any comments on the proposed process for making investment decisions about specialised services?**

We acknowledge the reality that NHSE must first invest in those treatments given a positive appraisal from NICE, followed by NHS Constitution requirements and national priorities. However, this emphasises the need for national approaches (e.g. approach of NICE, setting national priorities through the Cancer Strategy etc) to be fit for purpose.

Cancer52 is delighted to be represented in the Taskforce charged with developing the 2015-2020 Cancer Strategy for England. The Statement of Intent, published in March 2015 (available at: [http://www.cancerresearchuk.org/sites/default/files/statement\\_of\\_intent\\_final\\_0.pdf](http://www.cancerresearchuk.org/sites/default/files/statement_of_intent_final_0.pdf)) notes that:

- Currently around half of cancers are rare or less common
- Survival in pancreatic cancer, oesophageal cancer, most brain tumours, and many of the rare and less common cancers, remains stubbornly low (in comparison to more common cancers such as breast cancer). The Statement of Intent calls for research efforts to address these needs to be maintained
- Challenge in diagnosing cancer, where those with rare and less common cancers or where symptoms are less specific visit their GP three or more times before referral for a diagnostic test
- Patients with rare and less common cancers report lower rates of satisfaction than those with common cancers

Cancer52 is optimistic that this Strategy will set out a national (England) vision for cancer, but we also believe that there is still more work to be done to make sure that the NHS meets the needs of those with rare and less common cancers. We hope that the Statement of Intent for the Cancer Strategy does not follow the example of the Statement of Intent for the Strategy for Rare Diseases. To date, the Statement of Intent for Rare Diseases, published in February 2014 (available at: <http://www.england.nhs.uk/wp-content/uploads/2014/02/rare-dis-stat-intent.pdf>) has not been followed by a plan for implementation. Progress by NHSE has been described as “disappointing” by the Genetic Alliance (available at: <http://www.raredisease.org.uk/documents/Website%20Documents%20rduk-activity-report-2015.pdf>). England has also fallen behind our neighbours in the UK.

We ask NHSE to clarify how and where in the process consideration will be made to explore the scope to apply Commissioning through Evaluation. We see this as potentially providing an opportunity to provide access whilst also learning more about new services and treatments. This is particularly relevant, as recognized in the Five Year Forward View, when RCTs make testing new treatment approaches difficult due to small populations (see <http://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf>).

The consultation states that the CDF remains outside of these arrangements as a politically driven approach. The CDF remains an anomaly that needs to be urgently addressed.

The consultation supporting documents include reference to a Clinical Evaluation Committee. We would like NHSE to publish the Terms of Reference for this committee, its membership, and to clarify how it can build the clinical policy and service specification and formally support it as suggested by Decision Event 5, when they do not appear to be in the stage of Phase III (clinical build).

#### **4 Are there any additional stages in the process that we should consider introducing?**

Ongoing monitoring and review of service delivery should be linked to investment and disinvestment decisions. These do not appear to be clearly identified but we urge NHSE to consider during its investment decisions how to ensure that a service/treatment is used most efficiently. We are delighted that the future of the Cancer Peer Review Programme is now secure – albeit in a revised format and a remit that extends beyond cancer. It is our very strong view that we must ensure that patients (and carers and families) have an important role to play in ensuring that services meet the highest standard possible.

We also note that the process as it is outlined in the supporting documentation do little to make it clear who is really driving decisions to invest (or not to) and without clear reference to involvement of CCGs in specialised commissioning.

#### **5 Are there any additional stages in the process, in addition to those described, where engagement with patients and the public should take place?**

Cancer52 expects that NHSE should provide opportunities for engagement with patients and the public throughout the process (with recognition that not all patient groups and/or individual patients will be able to always take them up – nevertheless the opportunity should be provided). The consultation has not set out where they are excluded. We ask that NHSE confirm that patients and the public will have opportunities to engage throughout the process. We also ask that NHSE confirm whether or not the Clinical Appraisal Panel includes a lay/patient representative(s)?

We would also urge NHSE to move beyond engagement to true involvement. A practical suggestion is that NHSE invite a relevant patient representative as a secondee when considering investing in new services/treatments. Such an opportunity may not always be possible where there is no patient group, or where the patient group is small and with limited time and resources, nevertheless providing the opportunity signals a real willingness for NHSE to involve patients and not just engage.

We also note that as science progresses that there may be times when investing in a service may need to bring in expertise from more than one Clinical Reference Group (an example is BRCA testing for ovarian cancer, but we expect such examples will increase over time). We ask that NHSE identifies such occasions proactively and clearly identifies a lead CRG so that patient groups are clear who to engage with.

#### **6 Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the principles and process that we have described.**

The devil is in the detail as ever. However we have already noted our concerns about inequalities; more than half of cancer deaths occur in the rare and less common cancers and rare and less common cancers affect nearly 50% of those diagnosed with cancer. The National Audit Office in January 2015 also highlighted what they describe as ‘significant variations in outcomes and access to services’ (see <http://www.nao.org.uk/wp-content/uploads/2015/01/Progress-improving-cancer-services-and-outcomes-in-England.pdf>). There remain many of the rare and less common cancers where there have not been the improvements in survival seen in others; this variation and underlying unmet need must be tackled.

**7 Are there any other considerations that you think we should take into account when developing the principles and process about investing in specialised services?**

We ask that NHSE publicly commits to a planned review of these principles and processes within two years of their implementation.

**8 As well as hearing your views on which treatments and services NHS England should prioritise for investment, we are also keen to hear your views on NHS England’s rolling programme of service reviews on how specialised services are delivered. If you have any views on which services should be prioritised for a service review in 2015/16, please tell us**

Our individual members will respond as appropriate to this question.

**9 Before completing the survey you must declare any financial or other interests in any specialised services. For example, if you are responding on behalf of a voluntary organisation and your organisation received any funding within the last two years (including sponsorship or grants) from companies that manufacture drugs or treatments used in the treatment of specialised services, you must declare this. If you are a commercial supplier to the NHS of specialised services this should also be specified.**

We have provided a declaration of financial and other interests below:

Cancer52 is a company limited by guarantee. Its registration number is 07994413.

In the year ended 31st March 2013 Cancer52 received £23,500 from pharmaceutical companies and £64,875 in the FY ending 31st March 2014.

The companies who have supported Cancer52’s work include Amgen, Boehringer Ingelheim, Celgene, Novartis, Pfizer, and BMS.

We ask that NHSE and NHS responses to all future consultations must equally make a financial and other interests declaration, and that these are published.

NHSE could also demonstrate transparency by disclosing the names and roles of all those NHS and NHSE submissions that formed the majority (107 out of 189 taken from <http://www.england.nhs.uk/wp-content/uploads/2014/11/cdf-consult-rep.pdf>) responses to the 2014 CDF consultation. We note that NHSE is less transparent than NICE in terms of consultation respondents and the content of consultation responses, for example NICE published the full details of responses to their consultation on Value Based Assessment in 2014 (available from: <http://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/VBA-Consultation-Comments.pdf>).