NHS England: Consultation on proposals for a new Cancer Drugs Fund (CDF) Operating Model from 1 April 2016

Response from the Royal College of Radiologists produced collaboratively with the Royal College of Physicians London

1. **Do you agree with the proposal that the CDF should become a 'managed access' fund for new cancer drugs, with clear entry and exit criteria?**
   Agree

   Please provide comments to support your response:
   - The Royal College of Radiologists (RCR) understands the distress experienced by patients with cancer and supports the potential for them to have more timely access to promising new cancer drugs, particularly those which are likely to be approved by NICE for use in the NHS.
   - The RCR also acknowledges that NHS funding is finite and that the cost effectiveness of drugs needs to be considered. Furthermore, the impact on funding available for other cancer treatments and treatment of other conditions with equivalent impact on health status also needs to be considered.

2. **Do you agree with the proposal that all new cancer drugs and significant new licensed cancer indications will be referred to NICE for appraisal?**
   Agree

   Please provide comments to support your response:
   - The RCR considers it essential that all new drugs and drug indications should be scrutinised in an evidence based and transparent fashion so that NHS resources are used optimally for the benefit of all patients.
   - The main (and most challenging) thrust of the proposed changes within the consultation document, is the development of the CDF as a "test bed" to assess the "real world" benefits of recently licensed oncology drugs within the UK and thus to develop a Commissioning through Evaluation (CtE) approach.

3. **Do you agree with the proposal that the NICE Technology Appraisal Process, appropriately modified, will be used to evaluate all new licensed cancer drugs and significant licence extensions for existing drugs?**
   Agree

   Please provide comments to support your response:

4. **Do you agree with the proposal that a new category of NICE recommendations for cancer drugs is introduced, meaning that the outcome of the NICE Technology Appraisal Committee's evaluation would be a set of recommendations falling into one of the following three categories:**
   i)Recommended for routine use;
   ii) Recommended for use within the Cancer Drugs Fund;
   iii) Not recommended.
   Agree

   Please provide comments to support your response:
   - The RCR has concerns that for those drugs in Category (ii) it is unlikely that two years post marketing surveillance will provide data which had not been obtained in registration studies and thus there may be pressure to accept a lower standard of

evidence for some drugs. Therefore, the processes for analysis of outcome data and processes for removal of drugs from the CDF need to be robust.

- The traditional role of NICE is to evaluate available (usually published) evidence for its outputs. Although it is stated that there is an observational data unit within NICE, there is no information on how this will work and particularly whether its role will be in commissioning data collection/analyses or conducting these in-house. No details of previously completed analyses by this unit are provided. No details are provided on the structure, level of staffing, lines of responsibility and accountability for this observation data facility.
- The very rapid time frames required of NICE to deliver a provisional recommendation (rejection, adoption into routine commissioning or "conditional" approval (CtE)) before marketing authorisation and a definitive recommendation less than three months afterwards will be very challenging, particularly in the current financial environment.

5. Do you agree with the proposal that "patient population of 7000 or less within the accumulated population of patients described in the marketing authorisation" be removed from the criteria for the higher cost effectiveness threshold to apply?
Agree, provided rigorous criteria apply to all drugs and patient populations.

Please provide comments to support your response:

- The RCR considers it essential that patients with rare cancers have access to potentially effective treatment given the specific difficulties obtaining the required patient numbers to acquire robust data. An expert body of uncompromised and unbiased medical expert opinion may have important input to such evaluations. Different methodologies for analysis of outcome data may need to apply for drug treatments for rare cancers.

6. Do you agree with the proposal for draft NICE cancer drug guidance to be published before a drug receives its marketing authorisation?
Agree

Please provide comments to support your response:

- The RCR agrees with this proposal as it would optimise the chance of prompt drug availability for patients once a licence is obtained. However, it is essential this draft guidance remains confidential until after marketing authorisation, otherwise there may be pressure from pharmaceutical companies to defer entry into the process in the UK and thus potentially delay drug availability for NHS patients. It is also considered essential that the discounted price arrangements to reach desired Quality Adjusted Life Year (QALY) should also remain confidential.
- The RCR is also concerned that this proposal could provide the opportunity for those who may not be bound by clinical evidence of benefit and cost effectiveness considerations, unduly to influence final NICE guidance. The proposed timelines are very tight for an expert review group to be formed, meet and report.

7. Do you agree with the process changes that NICE will need to put in place in order for guidance to be issued within 90 days of marketing authorisation, for cancer drugs going through the normal European Medicines Agency licensing process?
Agree

Please provide comments to support your response:

- The RCR is concerned that given the number of drugs becoming available or new licensing indications of existing drugs, NICE may not be able to deliver on tight timelines required for decision making. However, given the publicity associated with the introduction of new drugs, it is reasonable to apply the 90 day time frame.

8. **Do you agree with the proposal that all drugs which receive a draft NICE recommendation for routine use, or for conditional use within the CDF, receive interim funding from the point of marketing authorisation until the final appraisal decision, normally within 90 days of marketing authorisation?**
   Agree, provided it is clear and guaranteed funding is withdrawn after negative decisions. There is a clear onus on clinicians not to promise the drug until after the final decision

   Please provide comments to support your response:

9. **What are your views on the alternative scenario set out at paragraph 38, to provide interim funding for drugs from the point of marketing authorisation if a NICE draft recommendation has not yet been produced, given that this would imply lower funding for other drugs in the CDF that have actually been assessed by NICE as worthwhile for CDF funding?**

   - A cautious approach should be adopted. The RCR has concerns regarding the lack of robust data for some drugs which have gained marketing authorisation, difficulty with data collection and timeframes post marketing and "flooding the system'' with drugs which have not been appraised.
   - Any funding must be on the basis of a NICE decision; anything else would encourage non-compliance with the process.
   - We recommend that clarity regarding timelines for technology appraisal is essential. If prompt decisions are not made, in the case of treatments for common diseases with a large number of potential patients, there is the potential for significant impact on an available, finite budget.
   - This should not be used as a default position by NICE if ambitious timelines and decision making cannot be achieved due to volume of work and lack of capacity to deliver.

10. **Do you have any comments on when and how it might be appropriate for the CDF in due course to take account of off-label drugs, and how this might be addressed?**

    - The RCR considers that given the difficulties in conducting trials and the long timeframe to recruit significant patient numbers in uncommon and rare cancers, adjustments in data quality and QALYS should be considered for these rare disease sites. A consensus view of a panel of expert clinicians regarding efficacy of specific drugs for rare indications could be considered.
    - There needs to be a process of flagging prescription of such drugs nationally. The funding for this would come from new Individual funding requests (IFR) arrangements.
    - NICE should consider how to support the evaluation of drugs for new indications which are no longer on patent, and therefore no longer supported by pharmaceutical companies.

11. **Do you agree with the proposal to fix the CDF annual budget allocation and apply investment control mechanisms within the fixed budget as set out in this consultation document?**
    Agree

    Please provide comments to support your response:
    - The RCR agrees with this proposal as the budget needs to be capped at some point, but the process must ensure equity of access for all patients.

- Given many competing pressures on the finite NHS budget and the need for equitable access to treatments across oncology and the wider NHS, it is essential that the CDF budget is controlled so that patients do not miss out on other interventions (curative radiotherapy/surgery, alternative treatments/supportive or palliative or rehabilitative care) because the oncology budget has been disproportionately used to support novel agents of limited cost effectiveness.

12. Do you consider that the investment control arrangements suggested are appropriate for achieving transparency, equity of access, fair treatment for manufacturers and operational effectiveness, while also containing the budget? Are there any alternative mechanisms which you consider would be more effective in achieving those aims?

- The RCR agrees that this proposal represents an improvement on the current system
- The two year window for post marketing data collection is likely to prove difficult and there are concerns regarding the robustness of data collection which will be the responsibility of the pharmaceutical company. The Systemic Anti-Cancer Therapy (SACT) database operational in England is ideally placed to record drug usage, efficacy, toxicity and outcomes.
- This provides the opportunity for pricing adjustment by pharmaceutical companies to achieve a cost per QALY of £25k-£30k for drugs with lower demonstrated cost effectiveness and to allow drugs to be used and post marketing data to be collected.
- Financial management will be complex. The time lines for NICE to give conditional approval, to agree data collection mechanisms, to "recruit" a sufficiently large cohort of patients to allow a reasonable prospect of a statistically robust analysis and the period of drug treatment then needed to reach useful and robust clinical endpoints mean difficult decisions will need to be made (in a very uncertain and rapidly changing environment) concerning the use of the limited resource available to conduct the observational analyses needed. Even in advanced malignancy when disease progression occurs early, it will be difficult to conduct a CtE analysis in less than three years. Drugs used in the adjuvant context cannot be realistically tested by this approach.

13. Are there any other issues that you regard as important considerations in designing the future arrangements for the CDF?

The RCR considers the following issues important:

- Support and funding for the Systemic Anti-Cancer Therapy (SACT) database and e-prescribing should be embedded in new arrangements to provide contemporaneous and reliable information regarding uptake of drugs within the CDF. There is very little detail on the shape of the data collection mechanism(s) and the data fields to be collected. The possibility of this being orchestrated by pharmaceutical companies is suggested but not confirmed. It is surprising that the existing SACT database is not mentioned in the report and no role for this database in the CtE process is suggested (see SACT summary below).
- In view of the current prominent focus on drugs, we need to invest in all aspects of diagnostics (including radiology and pathology) in order to use drugs appropriately and other treatment modalities i.e. surgery and advanced radiotherapy, which together contribute to cure in the majority of patients.
- Arrangements for the devolved nations need to be considered, given that they are all part of the NHS as the availability of the CDF is a significant cause of inequitable access across the UK. It will be important for NHS England to engage with NHS administration authorities in the devolved nations to explore whether a unified approach across the UK could be achieved.

- Sustainability – the RCR has concern that even with these new arrangements, the costs of novel agents will continue to spiral. Open, honest discussion between all stakeholders regarding how much the NHS (and the taxpayer) can afford to pay for cancer drugs, how they should be funded and what cannot be afforded could well be needed.
- Monitoring of drug efficacy during treatment – the RCR recommends consideration of the arrangements for ensuring that a drug is not continued if the disease is progressive and/or there is unacceptable toxicity. The RCR questions whether systems and clinical protocols are in place and enforced in order to ensure that such drugs are only used when clinically appropriate. The RCR considers that the SACT database should continue to be developed in order to contribute to this role.
- The time between the end of the consultation and the "new" CDF is six weeks. It will be difficult for NHS England to review, discuss and respond to the comments that will be received in this period of time. It is very unlikely that a definitive plan for CDF in April 2016 will be possible, if the input to the consultation document is to be taken seriously.
- NHS Trusts are required to provide significant amounts of data for central purposes and the burden that this places on them is significant. It is clear that the availability of a CDF drug given "conditional" approval by NICE will be contingent on the ability of that trust to provide the necessary data to allow assessment of outcome. If the infrastructure to achieve this is not in place, this may mean that many CDF drugs will not be available in many Trusts. The prospect of patients needing to travel to other Trusts to access drugs with conditional CDF approval comes with significant downsides in terms of (dis)continuity of care, a negative impact on care pathways, destabilisation of existing clinical services/trust finances, clinician dissatisfaction and the spectre of postcode availability.
- The SACT database is not without its problems. Data quality assurance and ascertainment are concerns and electronic prescribing is insufficiently used around the UK. Nevertheless, the majority of data that is required for a CtE approach is already collected within SACT and an approach of a bespoke additional CDF-orientated data collection requirement on top of the already required data fields for SACT would minimise the additional work involved in CDF-CtE data acquisition.
- The RCR strongly supports the continued evolution of the SACT database in order to provide robust data on activity, into which could be incorporated the evaluation process required by NICE, provided sufficient infrastructure support and funding.

14. Do you agree that, on balance, the new CDF arrangements are preferable to existing arrangements, given the current pressures the CDF is facing?
Agree, but subject to the comments below.

Please provide comments to support your response:

- It is important to improve patient education and understanding of the short life gained at the cost of significant toxicity which may impair rather than enhance the remaining quality of life. The alternative of care and quality time in a supported family/community environment may be the much better option. Patient advocacy groups, cancer charities, voluntary sector, pharmaceutical companies and clinicians all have a responsibility to define clearly the cost-benefit ratio of these drugs in non-jargonised terminology that patients can understand, without patients feeling they are missing out on a so-called "wonder drug" because of perceived cost constraints. All stakeholders should advocate responsible prescribing and a balanced approach to decision making.