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NHS England: Investing in specialised services

We broadly agree with the NHS England's proposals regarding how decisions are made when investing in specialised services. However, we feel that while the process is transparent, even more emphasis should be placed on patient engagement and a seamless patient pathway experience.

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

We are in agreement with most of the proposed principles set out in section 19. We agree with the principles in Section 19(i) of transparent decision making, involving the diversity of stakeholders and taking into account all relevant guidance in making prioritisation decisions.

We support the provision that there is a deliverable and measurable benefit to patients (Section 19(ii)(b)) but suggest that when this is applied to genetic and genomic testing, there are sometimes grounds to extend the assessment of benefit beyond the patient to other family members (such as in familial hypercholesterolaemia, where the NICE evaluation for genetic testing for that condition included cascade testing of relatives). We would not want the wording of this section to preclude wider familial interests if appropriate.

We agree that the normal gold standard of randomised controlled trial evidence will not be possible for many rare diseases due to their rarity but that this should not limit access to the most effective treatments

In relation to Section 19(iii)(a) we endorse the stated position of according priority to treatments or interventions for rare conditions even where there is limited published evidence on clinical effectiveness arising from the rarity of the condition which limits the availability of data. We agree that the normal gold standard of randomised controlled trial evidence will not be possible for many rare diseases due to their rarity but that this should not limit access to the most effective treatments that are available - even if they do not meet the usual gold standard for evidence.

Regarding Section 19(iii)(b) we are in full agreement that treatments should be provided in an equitable manner, so that all patients fulfilling

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the clinical criteria for treatment will have access to it. However we would not wish this criterion to exclude a risk stratification process which uses genomic information to inform which patients are likely to respond most effectively to treatment, or which patients might benefit most from a given intervention. This might include the use of a companion diagnostic test to determine suitability. Since it is likely that these forms of targeted treatment will increase in the future, it is vital that the definition of 'same patient group' is not interpreted too broadly, in ways that would exclude these approaches.

Whilst we recognise that this consultation is for specialised services only and therefore not applicable to a full range of professionals, a key issue to ensuring universal accessibility to the most effective treatments appropriate to the patient's genotype or tumour genotype will depend on the full range of clinical professionals having sufficient awareness of genomics. Ultimately this will require NHS England to have systems in place to ensure that less specialist practitioners will have the competences to access appropriate services for their patients.

Concerning Section 19(iii)(c), currently there are wide disparities in the take up of genetic testing (*Promoting Gene Testing* 4th Report of UKGTN, November 2014) which underpins much of genomic service provision. So according priority to treatments and interventions that are likely to reduce health inequalities is welcomed.

Section 19(iv)(b) provides that treatments and interventions will only be commissioned if they are affordable within 'its relevant budget'. There is increasing evidence to suggest that genetic and genomic testing as a first line approach will often reduce costs through enabling a diagnosis to be reached more rapidly. This is especially true with the reducing costs of next generation sequencing (NGS) genomic testing and the ability to offer multiplex testing. It will also reduce the need for more invasive testing and so will also be more acceptable to patients. Thus making genetic and genomic testing available will enable resources to be released that would have been taken up by a succession of tests and consultations allowing these resources to be reinvested in health care. However it is also often true that the reduction in costs (and in funds that are released through the adoption of genetic or genomic tests) are within other budgets such as the relevant clinical specialty or another department such as radiology. Thus the requirement that savings are made 'within its relevant budget' may be difficult to achieve with the substitution of a genetic / genomic test for other investigations, unless budgets are interpreted in ways that straddle clinical silos.

Do you have any comments on the proposed process that we have described for making investment decisions about specialised services?

We support the proposed approach to evidence review and decision making. It appears systematic, transparent, independent and rigorous particularly the externally commissioned independent evidence review. However, care should be taken to ensure that the valuable clinical input and oversight of CRGs is maintained.

It is unclear how the commitment to rare disease services will be addressed in the sequence order of prioritisation. For example, in Section 20, it appears that the majority of rare disease service developments could fall in orders 3 and 4. The proposal does not indicate whether a proportion of funding will be allocated to lower orders or whether investment in such order services will be dependent on resources available after investments have been made for proposals addressing order 1 and 2 requirements. If no prior allocation is made, we are concerned that funds could be exhausted by higher order priorities meaning that insufficient funds would be available to meet demands for rare disease services.

In the interests of being seen to be equitable and transparent, it would be helpful to provide a rationale for why the Cancer Drugs Fund is regarded as being 'outside these arrangements'.

Are there any other additional steps in the process that we should consider?

As part of fourth order specialised service developments, specialised services should be developed that are a part of the patient pathway that starts in primary care and where appropriate may lead to highly specialised services to ensure that patients are able to access the range of services at the right level of specialism according to their needs. Developing integrated pathways that transition primary, secondary and tertiary care, will be a good way of ensuring a patient-centred approach, and will help to avoid fragmentation of care (and budgetary priorities) described above.

We support the proposed approach to evidence review and decision making. It appears systematic, transparent, independent and rigorous

Are there any additional process steps to those defined where engagement with patients and the public could be most usefully carried out?

We support the extent of patient, stakeholder and public engagement that has already taken place and the extensive future engagement proposed in this process. Engagement with patients and the public is key to high quality service delivery at all stages in the process, and to building public trust and confidence. This is likely to become even more important in the future as increasing demands will be placed on limited budgets. For

this reason we recommend that there should be evaluation of each stage to examine how far this engagement takes place, how effective it is and whether there are ways in which it can be improved.

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

Principles and process should ensure that the patient pathway of a proposal is seamless between the different levels and elements of health and social care. Making sure that patients do not get lost as they transition between primary, secondary and more specialised care is vital. The transition between child and adult services is an area that requires more consideration: many care pathways struggle with this interface.

Before completing the survey you must declare any financial or other interests in any specialised services:

The PHG Foundation is an independent health policy think-tank that has a mission to foster and enable the use of scientific knowledge and technologies arising from biomedical science for the benefit of health and health services. More specifically, the PHG Foundation focuses on the way that new technologies, especially those relating to genomics, are translated within health services and on the impact of genomics upon clinical and public health services. The PHG Foundation has not received funding from companies involved in the manufacture of drugs or treatments. It also has no financial or other interests to declare in any specialised services.