University of Essex

Investing in Specialised Services

Analysis of Responses to an NHS England Consultation

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Health and Care Research Service

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2 Executive Summary

In January 2015 NHS England published a national consultation called *Investing in Specialised Services*. This national consultation document described the proposed principles and processes by which NHS England will make future decisions on investment in specialised services. The consultation sought views on the proposed principles, process and their likely impact on reducing inequalities; it was open for 90 days and closed on 27 April 2015. This report presents an analysis of the responses received to this national consultation.

Key Findings

- There was a high response rate (278) with responses representing a broad range of stakeholders including patients, public, professionals, charities and the healthcare industry
- There was broad general support for the principles although many respondents wanted more detail on these, particularly on how the principles would be weighted; there were various views offered on which principles should be given greater weight than others
- Questions were raised around the operational definitions of clinical effectiveness and value-for-money, these definitions being key to whether or not the principles and process would reduce inequalities
- Respondents generally acknowledged the necessity for a priority order and the statutory requirement to fund NICE approved treatments but many requested more detail on the proposed process and questioned how the proposed principles would be applied to it
- There were concerns about the efficiency of the proposed process and suggestions for streamlining and improving its efficiency were submitted (see Appendix IV)
- There were a range of views about the process of reviewing evidence and who should conduct this work; clarity was sought on this part of the process in particular
- It was felt that stakeholder involvement including patients and the public need to be wider and more embedded throughout the process; a common view was that CRGs in particular needed a review of structure, membership and support in order to be an effective conduit for stakeholder involvement and expert input

3 Analysis of Responses

In January 2015 NHS England published a national consultation called *Investing in Specialised Services*. This national consultation document described the proposed principles and processes by which NHS England will make future decisions on investment in specialised services. The consultation sought views on the proposed principles, process and their likely impact on reducing inequalities; it was open for 90 days and closed on 27 April 2015. This report presents an analysis of the responses received to this national consultation.

3.1 Principles

In the consultation document, NHS England set out four categories of principles:

(i) General principles as to prioritisation
(ii) Does the treatment or intervention work?
(iii) Is the treatment or intervention fair and equitable?
(iv) Is the treatment or intervention a reasonable cost to the public?

Stakeholders broadly ***supported the principles*** that were consulted upon and a number of additional principles were suggested. These were:

- Innovation should be prioritised
- NHS providers should be the providers of choice
- Pathways and local commissioning should be taken into account
- Early intervention and prevention should be prioritised, particularly interventions for children
- Patient choice should be enabled

Many respondents also provided further comments on the principles and these comments are detailed below.

3.1.1 General principles as to prioritisation

The consultation document detailed the following general principles:

NHS England will:
a) follow its normal good practice in making prioritisation decisions in a transparent way, documenting the outcomes at all stages of the process;
b) involve the diversity of stakeholders including the public in the development of proposals and take appropriate account of their views; and,
c) take into account all relevant guidance.

Respondents generally ***welcomed the commitment to the principle of transparency*** although there were questions about how this would be achieved in practice. However, these comments were more relevant to the actual process than the principle itself and they are therefore summarised in Section 3.2, Process.

A particular issue of concern relating to (a) above and also relevant to all principles more generally was the point about prioritisation decisions. It was generally felt that more detail was needed on this and there was a widespread call among respondents for ***clarity on the weighting of the principles and the scorecard***. Many referred to a previous unsuccessful scorecard method put forward for this and the need for this work to be further developed.

> *We appreciate that NHS England attempted to develop a scorecard to assist with this process and we would encourage them to continue developing a similar tool transparently alongside*

> *stakeholders. However, we would stress that this tool must also be subject to a separate public consultation. (Parkinson's UK)*

In terms of any eventual system of weighting and prioritising interventions, a number of respondents called for ***clarity on the different weighting of the four principles***, for example guidance on how many of the principles need to be met and guidance on whether any particular principles were deemed to be more important than the others (a particular concern seeming to be that 'reasonable cost' would trump other principles).

> *Is there to be a priority 'rating' between the principles? i.e. if the cost is deemed 'unreasonable' (and how this is measured) will it be discarded even if the other 3 principles are met? (Anonymous)*

The principle of ***consulting with stakeholders including patients and public was widely welcomed***. There were numerous issues raised about issues of process, nature, scope and transparency around public and stakeholder engagement that will be considered in Section 3.2, Process. In terms of the principle itself there were slightly contrasting views about the weight given to different stakeholder voices. There was a common view that the ***voices of the patients and public are not given sufficient weight***, for example:

> *The patient voice needs to be taken more seriously - it currently feels that although patients are included in many stages of the process their opinions carry little weight in the final decisions. (Patient member of a Clinical Reference Group)*

Several respondents emphasised that the ***views of patients with experience of the disease were important*** because "they are the ones with most direct experience of the relevant conditions" (Anonymous). However other respondents noted some caution on this issue, for example:

> *In the field of rare-diseases stakeholders must be selected carefully and representatives sought where suitable patient groups are not found. There is a danger that any prioritisation will be biased by those with more eloquent voices rather than those with the greatest clinical need. (Association for Glycogen Storage Disease UK)*

Principle (c) above, to take into account 'all relevant guidance' was queried across the board as lacking in specificity. It was widely felt that ***relevant guidance needs defining***. For example:

> *An important definition is what is included in 'all relevant guidance' as that will clearly impact decisions and behaviour in practice. For example, the inclusion of NICE guidance via Single Technology Assessment (STA) and HST routes. We assume this would be included but there is an important need to clarify on such points. (UK BioIndustry Association)*

Across all three principles (a, b and c) the clearest issues emerging were questions of balance in terms of the different principles. There is clearly a perceived need for transparency in terms of how the principles are weighted against each other in decision-making processes.

3.1.2 Does the treatment or intervention work?

The consultation document detailed the following principles about effectiveness:

NHS England will normally only accord priority to treatments or interventions where
a) there is adequate and clinically reliable evidence to demonstrate clinical effectiveness;
b) there is a deliverable and measurable benefit to patients; and,
c) they offer equal or greater benefit than other forms of care already in NHS use.
d) NHS England will not confer higher priority to a treatment or intervention solely on the basis it is the only one available.

Questions and concerns around the concept of 'clinical effectiveness' were a consistent response to this item. There were numerous comments concerning the ***need to consider critically the definition of clinical effectiveness***. The key points were that Randomised Controlled Trials (RCTs) are not possible for all conditions (for example because of rarity, the nature of the intervention, lack of funding); many interventions lack clinical trial data for children; the goals or outcomes of interventions are not universal and therefore not comparable; symptom measures normally take priority over quality of life in trials; experimental treatments would be precluded by the principle; clinical effectiveness should take account of qualitative data, patient experience and expert consensus:

> *How do you value independence, mobility? The ability to work, to live alone, to not suffer from depression, not to die? To climb stairs, make my own breakfast, drive a car. You need to completely understand every condition to UNDERSTAND the deliverable benefits for the patients. (Anonymous)*

It was also noted by several respondents that ***imaging, diagnostics and any interventions in the clinical pathway other than treatments were harder to assess in standard ways for clinical effectiveness***. Generally speaking, all of these concerns about the definition of clinical effectiveness assume that it refers to RCTs and NICE methodology. An alternative methodology to address many of these concerns was proposed:

> *When preparing the National Service Framework for Long Term Conditions in 2005, we faced precisely the same challenge. The Expert Reference Group for the NSF developed and validated a new typology for evaluating and collating this broader evidence base in a comparable way. The research quality evaluation is based on quality of research in relation to the most appropriate design, recognising that this will often NOT be an RCT. External evaluation has demonstrated that this typology is more appropriate than other systems (eg GRADE, SIGN etc) when evaluating a broader range of research design. I would suggest that serious consideration be given to using the NSF typology as the basis for evaluation and reporting of the evidence base. This means that the teams drafted in to undertake the evidence evaluations will need to be familiar with it. References and materials can be provided on request from myself… I am also happy to work with your research teams to explain how we approached this problem when developing the evidence base for the NSF in LTC and how to use the typology (which incidentally is also designed to be simple and quick to apply). (Former Chair of the Expert Reference Group for the National Service Framework on Long Term Conditions)*

Aside from these concerns about how 'clinical effectiveness' is measured, the related principle of prioritising 'patient benefit' was widely welcomed and was perceived as having a broader definition. Indeed many felt that ***patient benefit should be an over-riding principle, particularly above cost-effectiveness***:

> *The principle of delivering clear patient benefit is buried within the second principle, whereas it is our view that improving patient care and delivering patient benefit should be a standalone principle on which NHS England takes decision. By making such a principle distinct, NHS England would give a clear steer that it exists to improve patient care, as well as manage budgets. (Anthony Nolan)*

Many respondents were concerned about the final point (d) under this principle, that NHS England would not "confer higher priority to a treatment or intervention solely on the basis it is the only one available". Some respondents interpreted this to mean that treatments which were the only one would not be considered. It was felt that ***this principle could prevent innovation and would disadvantage conditions where there was only one treatment available***. Others recognised the issue to be more about semantics, in particular the problem of referring to 'higher' priority when, as noted above, respondents overwhelmingly called for more detail about relative weighting and prioritisation of these principles:

> *Why use the word "higher" here. This is a weighting that should be included in the proposed "scorecard methodology" (Anonymous provider)*

3.1.3 Is the treatment or intervention fair and equitable?

The consultation document detailed the following principles about equity:

NHS England:
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;
b) will only prioritise treatments or interventions where these can be offered to all patients within the same patient group (other than for clinical contra-indication).
c) will accord priority to treatments or interventions that are likely to reduce health inequalities, and will have regard to any relevant broader equality issues.
d) will take into account evidence of the impact of any prioritisation decisions on the wider health and care system, including societal impact.
e) will seek to advance parity between mental and physical health.

Some respondents queried the extent to which (a) above is consistent with ***the principle of clinical effectiveness*** *(principle c, section 3.1.2)*. This acknowledgement that it is difficult to have published clinical effectiveness evidence relating to rare diseases was welcomed, particularly by patient groups and charities representing rare conditions. However, there was also a call for this to be further justified on the grounds of fairness:

> *It is reasonable that you may not have such good data because of small numbers of patients, but are you also saying that a person with a rare condition deserves greater priority than one with a common condition? If so, that requires ethical justification. (Lay member of a NICE Technology Appraisal Committee)*

As noted in 3.1.2, the rarity of a condition is not the only reason there may be a lack of published clinical evidence. Issues of equality and disadvantage were therefore relevant to this statement and the issue of whether rare diseases are disadvantaged in general by this policy are discussed in Section 3.4, Reducing Inequalities.

There was support generally for the principle of equity, indeed some felt that this should be the over-riding principle (where others, as noted above wanted patient benefit to be the over-riding principle). However, the notion of 'equity' was consistently stated as requiring greater clarification. For example, a number of respondents called for the principle of ***reducing health inequalities to specifically refer to evidence and to include a definition of equity***:

> *It may be beneficial to make this statement more grounded by using wording such as '…the evidence suggests that they are likely to reduce health inequalities'. We believe there are strong evidence bases for what can make the maximum impact on reducing health inequalities (for example the LHO Segment Tool) and the wording could reflect this more effectively. There is also a potential area of clarification about what area of equity this is relevant to. Does health inequalities in this context relate to equity of access, outcomes, according to disease groups and conditions or deprivation or demographics. (Leeds City Council and Leeds Clinical Commissioning Groups)*

Principle (b) above, concerning being able to offer a treatment "to all patients within the same patient group", came in for significant criticism. Again, there was a perceived need to be more specific about how 'patient group' was to be defined. A number of respondents requested that this be clarified because depending on its definition it ***could lead to inequity and a contradiction to personalised medicine*** rather than equity:

> *In the emerging clinical environment where specific sub-groups of patients can be identified using diagnostic testing, the restriction that all treatments need to be available to all patients in a given cohort could be unfair and lead to some patients not receiving targeted therapy. Roche would like to suggest that this statement is made much clearer and that further clarity about how a patient group is defined [sic]. (Roche)*

The principle was also queried in terms of how absolutely it would be followed:

> *If a drug must be able to be "offered to all patients within the same patient group" does this mean that NHS England may say it cannot afford to offer everyone the treatment and so will offer no one it rather than stagger provision over a number of years? (Service User)*

In terms of impact on the wider health system and societal impact, there was general support for this as a principle, but it tended to be discussed as an issue for assessing value and cost rather than a matter of equity. Many respondents emphasised that as well as considering quality of life as an outcome (discussed above, see section 3.1.2), ***assessment of cost and clinical effectiveness should take into account a range of wider benefits*** including ability to work, reduction in benefits, potential to pay tax, fewer visits to the GP, reduced mobility costs, impact on carers and families, public health impact (preventing spread of communicable diseases) and long term cost savings (versus short term expenditure). However, a number of respondents noted issues around defining and measuring this impact:

> *The aim of taking into account evidence of the impact of decisions on the wider health and care system, including societal impact, is formidable. However, the currently available methods for taking account of societal impact are controversial and not straightforward as became clear during recent efforts to develop a system of value-based pricing for pharmaceutical products. It would, therefore, be important for NHS England to spell out what societal impact means and how the principles and processes proposed will help decision-makers make reasonable decisions in this regard. (King's College London and University College London Group on Social Values in Health Priority-Setting)*

There was also a question about whether taking social costs into account could potentially lead to inequity rather than equity:

> *So does that mean you would prioritise the employed before the elderly / unemployed because getting the employed back to work will benefit society? NICE struggled to introduce this wider remit last year and has gone back to the drawing board. One reason is that it inevitably discriminates unfairly against groups that contribute less/add more cost to society. (Lay member of a NICE Technology Appraisal Committee)*

Attaining parity for mental health was widely welcomed and many respondents felt that ***mental health represents one of the biggest areas of inequality presently***. Some were unclear how this principle would be applied and again the issue of relative prioritisation was a core concern:

> *Does this mean that mental health interventions will be afforded greater priority until parity is achieved or give parity from now on? How does this principle balance with health inequalities priorities where, for example, cardiovascular disease would receive a greater weighting. (Leeds City Council and Leeds CCGs)*

A broader issue relating to equity was an observation that ***care is needed to ensure stigmatised conditions are not at risk of unfair disadvantage*** (HIV, obesity, gender identity disorders and mental illness in general).

3.1.4 Is the treatment or intervention a reasonable cost to the public?

The consultation document detailed the following principles about cost:

NHS England will:
a) prioritise those treatments and interventions that demonstrate the greatest value for money; and
b) only commission for those prioritised treatments and interventions that are affordable within its relevant budget, and those that enable resources to be released for reinvestment.

Some respondents acknowledged the need for a prioritisation process to assist decisions about the use of finite resources. However, some felt that where a treatment meant the difference between life and death, cost should not be a factor. The principle of 'reasonable cost' attracted the largest range of comments. As noted previously, a particular concern was that ***saving money should not be an over-riding principle***. This idea attracted some strongly felt comments, for example:

> *Cost is the fundamental core of your principles. The principle to prioritise treatments and interventions that demonstrate the greatest value for money is not putting patients first. (Anonymous)*

Many supported the ***importance of cost-effectiveness***, however, and called for NHS England to use existing cost effectiveness data from HTAs/NICE and to ensure health economic evaluations were carried out for treatments where no analysis had yet taken place. Yet ***many respondents called for the concept of 'value for money' to be further defined and methodologies to be specified***. Issues around the wider societal costs discussed above are relevant here as is the related comment from respondents that the ***cost of not treating*** a condition should be taken into account. ***Many challenged methodologies such as QALY, associated with assessing value for money***:

> *Whilst of course we appreciate the financial situation of NHS England and of course support efficient use and deployment of public money, there is a real risk that the presentation of the concept of 'value for money' here lends itself to a prescriptive budgetary interpretation rather than a more holistic approach rooted in the needs of patients…. There is no clarification here on how value for money would be measured, over what timescale and to whom. For example the case for the inappropriateness of using cost per quality adjusted life year (QALY) for rarer conditions has previously been demonstrated. (UK BioIndustry Association)*

It was felt among many respondents that both ***'affordability' and 'relevant budget' required further detail***. There were queries about whether the budget referred to the whole specialised commissioning budget or programme specific budgets. With regard to the requirement for resource to be released by new investment, it was felt that:

> *These requirements would preclude introduction of "breakthrough" products and stifle innovation. (Tuberous Sclerosis Association)*

It was also noted that if this requirement was to be upheld, then ***principles and a process would be required for disinvestment to release resource***:

> *These principles should be applied to new investment opportunities, but also used to examine previously adopted policies to identify areas for disinvestment and for Cancer Drugs Fund. (An NHS Provider)*

Clarity was sought on the timescales for consideration of the cost of investing versus the savings from dis-investing:

> *It is not clear whether affordability applies to the following, single budget year or whether NHS England would take a longer term view of affordability if costs and savings were spread over many years. The Five Year Forward View introduced more long-term, strategic decision-making for investing NHS resources and the principles of this process should align with that ambition. (Gilead Sciences Inc)*

3.1.5 Additional Comments about Principles

In addition to comments relating specifically to the principles in the consultation document, some respondents provided further critique of or suggested additions to the principles set out.

It was suggested that, to counter the concern that innovation would be stifled by some of the principles, that ***innovation should in fact be prioritised***:

> *In order to reflect this we support the European Medicines Group and propose a new principle be added: 'When making prioritisation decisions, NHS England will take into account the degree of innovation that treatments and interventions represent compared to current clinical practice.' (Bayer Plc)*

There was a suggestion that an additional principle should be that ***where possible, NHS organisations should be the preferred provider***:

> *Specialised services should not be privatised. The NHS should be the preferred provider. Where possible they should be integrated into existing local or regional providers for maximum agglomeration economies. (Anonymous)*

A number of respondents emphasised the ***importance of considering or indeed commissioning the whole pathway***. Following concerns above relating to assessing clinical effectiveness of imaging and diagnostics, some respondents suggested principles to address this such as:

> *Does the proposed new diagnostic test/imaging modality/tracer demonstrate greater than or equivalent sensitivity and specificity when compared to conventional diagnostics?*
>
> *Does the proposed new diagnostic demonstrate a greater impact on patient diagnosis, staging, or response evaluation when compared to conventional diagnostics?*
>
> *Is the proposed new diagnostic the only way of diagnosing, staging and following up a rare condition?*

Related to this, it was also suggested that specialised commissioning principles should include the principle of ***dialogue and joining up with local commissioning and providers***:

> *There is a need to ensure that where specialised services are commissioned through NHS England there is sufficient dialogue at a local level to enable care pathways to be joined up and commissioned strategically; for example, commissioning bariatric surgery through specialised commissioning could lead to a disjointed weight management care pathway, with very little local flexibility to move resources around the local health and wellbeing system in order to invest in prevention and early parts of the care pathway. (Anonymous)*

A number of respondents argued that prevention was not given enough emphasis in the document and that there should be a ***principle to give priority to interventions that were preventative or provided early intervention***:

> *A focus on prevention/ risk identification for conditions should be seen as a priority- early care and intervention can reduce the impact to the NHS of a developed condition, especially in fields currently playing the poor cousin such as mental health. (Anonymous)*

Other areas where prevention was noted as important were cultural and social interventions to reduce communicable and inherited diseases.

More specifically, relating to early intervention, a number of respondents indicated that as a principle, they would propose that ***interventions for children should specifically be prioritised***. There were various manifestations of this view but broadly speaking the argument was both about life potential as well as cost saving in terms of early intervention. For example:

> *I believe that children should have priority in accessing new treatments for rare conditions - this is because they are less likely to have already damaged their organs, and will therefore benefit more in terms of years of normal life gained. (An NHS Professional)*

Patient choice was proposed as an additional principle:

> *Actelion suggests that NHS England consider the addition of a 'principle of patient choice' committing NHS England to offering patients a choice, where possible, to all effective, licensed specialised medicines. (Actelion)*

There were concerns expressed about the time efficiency of the process, which are discussed further under Section 3.2, Process. However, as an issue of principle, the point was made that ***time efficiency should be fundamental to ensuring patient benefit***:

> *There is no mention of any timeline in the principles, many treatments are vital for patient care and delays often result in irreversible damage. Therefore a principle on the importance of timeliness and efficiency in the development of policy documents should be included. (Gauchers' Association)*

3.2 Process

3.2.1 Prioritisation Sequence

In terms of process, the consultation document set out a sequence of prioritisation which were:

First Order. Service investment for NICE Technology Appraisals and the appraisals undertaken as part of the Highly Specialised Technologies Programme.

Second Order. NHS Constitution delivery requirements which affect specialised services.

Third Order. Developments to support national service strategies.

Fourth Order. All other specialised services developments.

A common concern about the sequence proposed was the budget likely to be available after the spending on First Order priorities:

> *It is stated that the estimated budget impact for NICE recommended treatments in 2015/16 is in the region of £270m and that NHS England is required to fund these treatments even in the absence of any allocated budget. What is this calculation based on, as we are concerned from the way this statement is worded that there is no money available to fund the implementation of NICE recommended technologies, let alone funds for specialised services developments that are Fourth Order? We are left with the impression that funding for specialised services developments will be heavily restricted. (Ethical Medicines Industry Group)*

Although many acknowledged the statutory duty of NHS England to commission NICE recommended treatments, there were also many who raised concerns about this. Many of these concerns related to the budget imposition this created and also to previous concerns expressed about the principle of clinical effectiveness in terms of the many reasons why RCTs and hence ***NICE guidelines may not exist in some areas***. There were also concerns about the capacity of NICE:

> *Whilst we would support the first order requirement given the statutory nature of NICE's guidance, it is important to note that not all new medicines are assessed under the STA or HST processes. Indeed, NICE has estimated that it will only be able to carry out approximately three HST evaluations per year. Therefore, any medicines not selected under the STA or HST processes automatically fall into the third order priority. (Shire)*

It was suggested that this ***prioritisation sequence would therefore be at odds with the principles of equality*** and would disadvantage particular interventions such as psychological therapies, HIV

treatments, interventions for children, small scale services, rare diseases, disabled children, innovative or new treatments, surgical interventions.

In addition to the over-riding concern about the priority given to NICE approved treatments and the budget impact of this, there were frequent comments about the ***lack of clarity over the distinction between third and fourth order interventions***. Some felt that the distinction could be relatively subjective and open to change and overlap. Some asked for a definition of 'national service strategy' and there were specific concerns raised about whether the Strategy for Rare Diseases would count as such a strategy.

3.2.2 Five Stage Process

The consultation document next described five stages of the proposed process for making commissioning decisions:

Scanning: coordinated at a Clinical Reference Group level. There are two published outputs from this stage – the list of potential clinical policies that are identified as 'Not being routinely commissioned' and the list of potential service specifications for commissioning.

Planning: where the National Programmes of Care, who coordinate the work of the CRGs into strategic groupings such as cancer, consider the proposals and select the ones that most fit the programme's strategic priorities. This will create an Annual Work Programme.

Building the clinical case: where the Clinical Reference Group works with stakeholders, including patients and the public, to define the clinical proposal. An independent review of clinical evidence will usually be commissioned. Finally, a Clinical Appraisal Panel will form a view whether a clinical case is made.

Impact analysis and consultation: where NHS England will develop, using the defined clinical criteria, a service impact analysis and hence a financial impact analysis. This will result in a final policy or service specification that can be considered for commissioning. The scale and duration of consultation will then be defined.

Governance: where the Clinical Priorities Advisory Group assures the Board that the process has been completed and recommends a priority order of commissioning. The NHS England Board approves the prioritisation. Commissioning against the priorities will be overseen by the Specialised Commissioning Committee.

Generally speaking, there was a wish from many respondents for more detail on all of the stages:

> *There is not enough detail in the consultation document about this process to comment. The descriptions of the parts of the process involved are very broad and do not really pin down who or how decisions about which treatments and services should be funded are reached. (Reverse Rett)*

Some respondents had received more detail on the proposed stages (for example, gleaned from consultation events and workshops) and commented in more detail on that information. In terms of 'scanning', respondents from the healthcare industry commented on the ***proposed use of UK Pharmascan as part of this scanning stage***. This was welcomed by healthcare industry representatives, but many felt this process could be developed further and be more efficient:

> *The ABPI welcomes the introduction of a systematic methodology for Horizon Scanning and would urge NHS England to work with the ABPI to further develop the role of UK Pharmascan so that it can provide the appropriate information in a commercially confidential space in a timely manner and therefore negate the need for the submission of Form A's. (Association of the British Pharmaceutical Industry)*

Others highlighted the need for an equivalent way of horizon scanning for medical technology and also issues around frequency of scanning (some thought monthly was too often and would not sync well with UK Pharmascan).

Clarity was requested on the ***respective responsibilities of the various groups involved in 'Building the clinical case'***. Many emphasised the importance of people responsible for ***reviewing this type of evidence having sufficient expertise*** and many questioned whether this should in fact be performed by the CRG given their level of expertise and to reduce the complexity of this part of the process, acknowledging they would need more support to do this. The resourcing and structure of CRGs is discussed further in Section 3.3, Stakeholder and Public Engagement.

> *We have questions about the Clinical Review Panel and its membership. If members are different to those clinicians who are part of the CRG, there is a risk of them being less expert. The sarcoma CRG for example, already has expert clinicians and expert patients as its members. We question the value of introducing another panel and independent review. (Sarcoma UK)*

There were diverging views about what sort of evidence should be considered at this stage and this relates to previous concerns raised about RCTs and published evidence. Specific to this part of the process, pharmaceutical companies were particularly concerned that unpublished evidence from manufacturers should be taken into account. These companies were also concerned, however, that manufacturer data must be handled with ***appropriate commercial confidentiality*** during this process and it was yet further proposed by Novartis that pharmaceutical companies could in fact be commissioned to produce the evidence reviews to save time and ensure manufacturer evidence is included with the appropriate level of commercial sensitivity. There were, however, voices that would oppose this suggestion:

> *Patient groups are concerned that pharmaceutical companies, essentially commercial organisations, could distort the setting of priorities by using their substantial marketing budgets in support of their evidence. (Royal College of Surgeons Patient Liaison Group)*

A number of respondents returned to the issue of NICE in relation to this stage of the process and suggested that ***NHS England should not be involved with evidence review at all as this should be left to the expertise of NICE***:

> *NHS England intends to assess clinical evidence when we believe that all such assessments should be undertaken by NICE and equivalent bodies in devolved administrations. In saying this, this does not take away for the need for NICE and others to be able to undertake assessments in a more appropriate and timely way, but we believe that NHS England is primarily a commissioning body and should focus its efforts on this, not assessment. (UK BioIndustry Association)*

Similarly many respondents called for NHS England to ***accept any medicine that had received approval from the European Medicines Agency***, rather than duplicating the work of reviewing evidence.

There was a common view that ***'impact analysis' occurred too late in the process***:

> *The impact analysis is developed at quite a late stage in the process and appears to take place after the investment has been recommended by the CRG. It is suggested that the CRGs should get involved in developing the impact assessment at a much earlier stage to ensure time isn't wasted and that their assessment is comprehensive. (Great Ormond Street Hospital for Children NHS Foundation Trust)*

There were also questions about how the financial impact assessment would be conducted and in particular, there was a concern that ***cost assessments should take into account clinical need and prevalence rather than historic uptake*** to ensure that uptake could be enhanced and all of the target population could be reached:

We would like NHS England to take into consideration the clinical need for specialised services based on the epidemiology of the disease or condition and NICE recommendations for particular patient cohorts, particularly for NICE Technology Appraisal approved treatments, where costing templates and projected patient treatment numbers already exist. Budget allocation and commissioning contracts/ service level agreements for these treatments are typically based on historical activity, rather than clinical need based on incidence and prevalence data. This has led to a slow uptake of cost-effective technologies against NICE forecasted levels. (Medtronic UK)

3.2.3 Decision Making

The NHS England consultation document referred to two further points about decision making within the process:

Embedded within the process are a number of places where decisions will be made. Each of these will be defined as 'Decision Making Events' and detail the elements such as who makes the decision, how the decision is made, and how the decisions are communicated.

One of the components under consideration to aid decision-making is the formation of a scorecard methodology. As part of the process for developing a prioritisation framework for specialised commissioning, NHS England will explore in 2015 the extent to which a 'scorecard' would be an appropriate tool to deploy in the proposed prioritisation process. If as a result of this further work a scorecard is considered ready for inclusion in the decision making processes in future years, then a specific consultation will be undertaken before introduction. The prototype scorecard developed and tested earlier this year will not be used in the 2015/16 commissioning round.

Broadly speaking there was ***disappointment among respondents that the proposed scorecard or other system of weighting was not included as part of the present consultation***. It was felt that this was so central to the principles and process under consultation that it was difficult to take a view on the document under consultation without it. There was also some concern that the scorecard or framework was not being developed with stakeholders, which is discussed further later in section 3.3, Stakeholder and Public Engagement. Specific comments about the eventual scorecard were that it should not be too simplistic:

It would be better to accord more flexible weightings based on the priority criteria of each specialised service rather than try to find "one model which fits all". Specialised services differ considerably and should be considered within that context. (Service user representative)

It was also suggested that it ***would benefit from an academic approach*** including a literature review on prioritisation processes used in other healthcare systems, peer review and the inclusion of academic expertise in its development:

It might also be helpful to have some ongoing outside "academic" expertise in evaluating any prioritisation process as it is taken forward. This will allow more objective evaluation and learning and be more likely to be seen from outside NHS England as a genuine attempt to make difficult decisions in a fair way rather than as sometimes perceived as just being about a money saving exercise. (Public Health England Commissioner)

Several respondents referred to the now disbanded ***Advisory Group for National Specialised Services (AGNSS) as having been a highly effective and efficient body for decision making*** in this field and it was suggested by many that that the "principles and criteria of the AGNSS framework would provide a useful guide for the development of NHS England's prioritisation framework" (Gauchers' Association).

In addition to consulting stakeholders or indeed involving them in developing the scorecard, it was also felt important for stakeholders including CRGs to be involved in decision making parts of the process, discussed further below in Section 3.3.1, Stakeholder Issues.

3.2.4 General Comments on the Process

A general comment about the overall process was that it was sometimes ***unclear how the principles had been applied to the process***, particularly relating to some of the issues noted above around equality. Again, this relates to the dominant concern about transparency and clarity in terms of the drafting and ongoing development of the operating principles.

There were particular concerns about the timeline and the efficiency of the process. In terms of the timeline, several respondents from the healthcare industry noted its ***incompatibility with timelines within the industry***:

> *The intended timings for the different stages of the process may require the submission of evidence and prices for medicines in advance of their availability. Final clinical trial data is usually only available a few months before European Marketing Authorisation and it is not until the license is given that the company can be sure precisely what the treatment will be indicated for, and by extension, the value and price. (Ethical Medicines Industry Group)*

Manufacturers therefore ***recommended a "rolling quarterly process"*** to avoid issues around yearly cut-off points and potential delays in the process which could lead to long delays in patients getting access to medicines.

It was frequently noted that ***the process overall was complicated and likely to be inefficient***. Novartis presented a detailed calculation of likely timescales suggesting a 'best case' of 35-43 weeks rather than a year to complete all the steps.

> *We believe the proposed process appears too long, complex and bureaucratic. Importantly, there is no indication as to timescales, something we would wish to understand in context of how many different stages, actors and decision-points there are in the process. (Pfizer)*

The ***Specialised Healthcare Alliance (SHA) enclosed with their submission a proposed alternative process*** described as "a streamlined yet robust process capable of delivering decisions with an annual planning cycle and more swiftly when required". This process can be found in Appendix IV. Several respondents who are also members of the SHA noted their support for this alternative process.

As noted previously, it was felt to be an important principle that processes should be time efficient. These issues concerning the complexity of the process were therefore important to respondents for various reasons not just in relation to practicality and to be aligned with industry cycles, but also to ensure timely patient benefit. There were therefore also calls for ***an interim process to enable patients to get urgent access to treatments while commissioning decisions were pending*** and for low-cost interventions to be fast tracked:

> *Where appropriate a system needs to be in place to ensure that patients in urgent need of a treatment proven to be beneficial (e.g. Already licensed) have access to the treatment while a decision about whether to fund it are being considered. (Tuberous Sclerosis Association)*

Related to this was a common view that the ***current process for Individual Funding Requests which might be viewed as such an interim process was inadequate for this purpose*** and clarity was sought on how this fitted with the current policy under consultation. Similarly, many respondents sought ***clarification on the In-Year Service Development process***, ***Commissioning through Evaluation and Early Access to Medicines Scheme*** and how they relate to the current proposals:

> *Federation members have expressed disappointment that other generic policies such as those governing Individual Funding Requests (IFRs) and In-Year Service Developments do not form part of this consultation. These should be reviewed and consulted on as a matter of urgency. In particular, problems arising from the existing IFR policy have often resulted in patients being refused treatments which they would have received under the previous IFR system. This situation is exacerbated by the time taken to develop commissioning policies. In this*

context, a compassionate use policy should be developed to bridge the gap between national policy development being triggered by 20 approved IFRs and that policy being finalised. (Federation of Specialist Hospitals)

We ask NHS England 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. (Cancer52)

There were also calls for clarity around other immediate ***interim arrangements for decision making for treatments considered to be 'stuck in the system'*** and where decisions have been pending while new policies are drawn up. Specific examples given were gender identity services, ultra-orphan medicines, Duodopa, Translarna, Vimizim.

3.2.5 Additional Stages Required

Although the majority of respondents agreed that the process was complex and should have fewer stages rather than more, there were nevertheless several suggestions for additional stages:

- ***Pre-scanning stage*** "to formalise the process for communicating all proposed service changes to CRGs for consideration" (Children's Hospitals Alliance)
- ***Preliminary evidence review*** by CRGs to "ensure all decisions are based in evidence of patient benefit, but also could significantly reduce the resource needed for the formal evidence assessment, as the work will have already been started" (Anthony Nolan)
- ***Risk assessment*** to review impact on patient safety (Tamba)
- ***Transition stage*** for "trialling the process" and "staff training" (Drugs company employee)
- ***Appeals process***: this was a majority view among many respondents and the proposed mechanism for appeal in the document was widely viewed as unacceptable.

  Many of the decisions which NHS England will take through the prioritisation process prove contentious. The inclusion of a formal appeal process, perhaps modelled on the appeals process operated by NICE – and open to both members of the public and other stakeholders (including manufacturers) – would help to insulate NHS England from the risks of formal legal challenge, and of the extra costs associated with it. (AbbVie)

- ***Implementation stage***: this was also a strong theme and reflected concerns that national commissioning policies are not always implemented systematically across the regions and so implementation should be monitored and be a formal part of the commissioning cycle

  Specific measures should be introduced to ensure compliance with NHS England service specifications and commissioning policies, including patient access to nationally-commissioned specialised medicines. These measures ought to be enforceable and be associated with incentives and/or sanctions. (ViiV Healthcare)

In addition to these proposed extra stages to the process, respondents also suggested separate processes should be devised for some aspects of specialist commissioning:

- ***Process for decommissioning and reviewing existing services***:

- ***Separate process for imaging and diagnostics*** (given the concerns noted previously about the bias in the principles and processes towards medicines).

- ***Separate process for rare diseases***. This was more commonly called for explicitly by respondents in the Healthcare Industry, although respondents from other areas also noted problems in the process associated with rare diseases implying a separate process may be required:

Rare and complex diseases: some aspects of the process might not be appropriate for specialised services for rare and complex conditions. (NHS Providers)

3.3 Stakeholder and Public Engagement

3.3.1 Stakeholder Issues

A key issue relating to stakeholder engagement was who should be included as a stakeholder. Issues around defining patient and public representation are discussed in Section 3.3.2, Patient and Public Engagement Issues. In terms of clinical representatives, there were concerns raised about the ***diversity of expertise required***:

There is insufficient engagement of clinicians in the process from general practice and general medicine. If only specialists are engaged in the process, NHS England will potentially get a biased view from the medical profession. (An NHS Professional)

There were also frequent calls from those in the healthcare industry for ***manufacturers to be included as stakeholders***:

AstraZeneca requests that NHS England specifically recognises the role of a manufacturer of a novel medicine as an Expert Stakeholder member of the CRG working group. A global pharmaceutical manufacturer is, by default, the 'expert' in regards to the supporting clinical data for a new medicine or indication. (AstraZeneca)

Other potential stakeholders put forward:

- Health Education England
- Trade unions
- Assistant Health Practitioners
- Clinical scientists
- Social care representatives
- Local/regional representatives (e.g. CCGs, local authorities): this was widely considered important as long as this occurred at the right level and right time in the process and was relevant to issues discussed previously in terms of ensuring joined up pathways:

  We would like to ensure that CCGs are able to engage with the new processes but using a 'right time - right level approach' and would be happy to work with NHS England to shape that. (NHS Clinical Commissioners)

Clinical Reference Groups (CRGs) were regarded as central in terms of the process of stakeholder engagement. However, it was widely noted that ***CRGs may need better support and a review of their role and structure***. It was noted that the proposed process would increase the role of the CRG leading to the need for increased resourcing:

There is currently insufficient resource allocated to CRGs despite their prominent position in the specialised commissioning system. Over-work has already led to bottle-necks and some CRGs are under considerable strain resource-wise. The proposed process requires even greater time commitment from the CRG and due consideration should be given to appointing a full time coordinator role for each CRG. (ViiV Healthcare)

It was also widely felt that the ***membership of CRGs required review and terms of reference in order to ensure consistency, adequate representation of all stakeholders and avoidance of conflict of interest***:

> *At present, the level of stakeholder engagement offered varies significantly from CRG to CRG, and for NHS England's new prioritisation process to rely on significant input from CRGs, they must all maintain the same standards and processes for stakeholder engagement. (Anthony Nolan)*

> *CRGs have an instrumental role in the commissioning prioritisation process. It is therefore absolutely vital that their governance arrangements (particularly membership and terms of reference) and the outputs they generate are publically available to prevent the risk of undue influence and/or conflict of interest. (Association of UK University Hospitals, AUKUH)*

Many respondents noted that the ways in which stakeholders could input to the process were opaque and requested ***clearer mechanisms for providing input and views***. There was a widely held view that the internet was core to this process and several respondents requested that webpages be created with comment facilities to allow for ongoing input from stakeholders. The website provided by NICE for this purpose was referred to as a good example. There were slight variations on this concept, for example one suggestion was that CRG websites should enable this while another was that NHS England should provide this facility directly:

> *We recommend that NHS England creates a web page for each policy proposal, navigable by PoC and CRG, so that stakeholders and the public can engage with the process via a 'comments' function. To be useful, this would need to be updated within 10 working days of decisions being taken. (Novartis)*

The issue of web facilities for engagement is discussed further in relation to patient and public involvement below. Remaining on stakeholder engagement more generally, there were many calls for ***stakeholder involvement to be clearly demonstrated and documented throughout the process*** to ensure that views are not just gathered but are seen to have had an impact on the process:

> *We would therefore ask NHS England to set out in much greater detail how and when they will take account of stakeholder views at each stage of the process. In addition, they should make public how each stakeholder view has impacted decision making and we point them again to NICE as an example of how this might be done. (Shire)*

It was generally felt that ***stakeholder involvement should take place from the very beginning of the process (scanning) and throughout the process including reviewing the evidence***. Some respondents commented that it was not clear from the consultation document whether or not this was intended. Some interpreted the process as detailed to indicate that consultation would only take place late on in the process in stage four (Impact analysis and consultation).

The above concerns about clear mechanisms and documentation of stakeholder impact were related to a broader theme of transparency. Although the principle of transparency was very welcome as noted previously, there were ***questions about how the principle of transparency would be implemented***. This was a very strong theme and felt to be a vital area of improvement in order to gain stakeholder trust in the processes. An example of the strength of feeling on this issue is indicated below:

> *The lack of apparent transparency has brought fear and a degree of resentment from patient groups affected by these decision processes primarily from the ultra-rare diseases communities who fear that they do not get justice, a fair hearing etc. all evident of the experience of marginalisation. NHS England needs to ensure that such hierarchies are addressed, and appropriate accommodations are made within any evaluation process in order to openly demonstrate that every effort is made not to marginalise. (Anonymous)*

There were many ***suggestions on how specifically transparency could be improved***:

- Publication of all key appointments within NHS England and structures within the specialised commissioning directorate
- Consult urgently on the scorecard
- Hold Programmes of Care boards in public
- 'Not routinely commissioned' list to be accessible on the website and updated at least monthly
- Improvements to the website to include the facility described above but also to publish minutes of all meetings and agendas of the following within 10 days of the meeting including:
    - CPAG
    - National Programmes of Care boards
    - Specialised Commissioning Oversight Group
    - Specialised Commissioning Committee
    - Clinical Reference Groups
    - Decision Making Events
- A clear up to date timeline including progress on every policy, for example, use of a "tracking system using a Unique Reference Number (URN) associated with each policy in development so that stakeholders can actively track where a policy, whether in development or under consideration, is in the process and the likely timeframes for a decision to be reached." (Actelion)
- Accessibility of information (to include access for deaf sign language users)
- Copies of all relevant documents available to the public on the website on an ongoing basis (not just during consultations)
- Clear contact details for the relevant commissioner or team relating to each policy in development
- Timely communication of results of all Decision Making Events to all stakeholders with clear rationale for each decision provided
- "Total transparency about private funding streams and why private providers are chosen over NHS bidders. If the service is picked up by a private provider then require to be informed which MPs and Lords are involved in that company."(Anonymous)
- Be open about investment decisions and mistakes
- Current up to date public information on all treatments which are available through specialised services to enable patient choice
- Avoid pre-empting the results of stakeholder consultations by moving forward on policies prior to the end of the consultation

3.3.2 Patient and Public Engagement Issues

As with broader stakeholder issues, there were also a range of views on who specifically should be included as public and patient representatives. There was a view that ***carers are not currently involved sufficiently in the process and should be***. There were also issues raised about the diversity of patients and public representatives, for example ***that general public views should be sought as well as views of those who have experienced the illness directly***.

In part, respondents were of the view that ***views from the general public were necessary to ensure that personal narratives from specific individuals or groups did not have undue influence*** within the process.

In terms of mechanisms for patient and public engagement, there were several respondents who noted that this should occur through Clinical Reference Groups and ***that if CRGs are appropriately structured and supported then this was an adequate mechanism*** without requiring further structures.

> *The patient and public voice should be fed through via the CRG. The Chairperson of a CRG is important in allowing the patient and public voice to be heard and their ideas integrated into*

> *the specification. Ensuring that this is the case is the most effective way of ensuring that patient engagement is reflected in the specification and thus during the stages in the process - especially if further interaction is enabled during the process between CRG and those making investment decisions. No further separate engagement should be required. (Service user representative)*

Nevertheless, there was a relatively strong theme that emerged which emphasised the need for ***better structures for public engagement and to involve wider representation from the public***.

> *When engagement is carried out, there is an urgent necessity to ensure involvement with people from different parts of the community is carried out. This includes reflecting the differing health and social care needs of marginalised groups, including but not limited to, people from Black minority ethnic communities. Effective and meaningful engagement with a range of groups should be mandatory, not an option. (MIND)*

It was noted by a number of respondents that the ***register of interested stakeholders held by CRGs was too passive a mechanism*** for identifying appropriate representatives and that more proactive methods were required. There were various suggestions for how to proactively reach diverse sections of society including:

- Make use of engagement structures within local communities through CCGs and local authorities
- Send advertising materials to schools, colleges, universities, GP surgeries, householders directly, local church halls
- Ensure venues for engagement events cover all regions and consider public transport links
- Commission BBC programmes
- Use local champions
- Use existing organisations and mechanisms e.g. Healthwatch, NHS Assembly, National Voices, Citizen and Patient Panels
- Use accessible methods of consultation rather than questionnaires e.g. Citizen Juries, focus groups, Citizen Councils (used by NICE) to help ensure involvement is not tokenistic

It was also noted by respondents that there should be a code of conduct for patient and public engagement and that training should also be provided. Specifically, some respondents referred to ***a 'Compact' agreement in use in other public sector engagement and call for this to be adopted by NHS England***.

As with stakeholder engagement generally, there were many calls for ***patient and public involvement to be part of the whole process from the very beginning and at every stage***, rather than just as part of a consultation stage. The view below was echoed by many respondents:

> *In order to harness the full potential of policy co-design, engagement with patients and the public should be a continuous process. There is a place for formal consultation but this must be alongside continuous and meaningful patient engagement at all stages of policy design and decision making. (Boehringer Ingelheim)*

In addition to involvement in all the proposed stages, there were also ***calls for patients and public to be involved in development and consultation on the proposed scorecard methodology and also on the appeals stage*** which is an additional stage requested by many respondents as discussed previously.

3.4 Reducing Inequalities

Some respondents felt that the proposed principles and processes would, if followed properly, ***help to reduce inequalities***. However, a number of concerns about equality have been drawn attention to throughout the analysis already, particularly concerns about the prioritisation of NICE approved

treatments which relates to concerns about the concept of clinical effectiveness. As noted previously, together, these were seen to create ***inequality for a range of groups, particularly those with rare diseases, those with mental illness, children and children with disabilities and will create bias towards drug treatments generally over imaging, diagnostics, prevention and small or developing services***. For example,

> *At every stage of the proposed principles and process, the questions and aspirations are focussed on treatments and interventions. This creates inequality and bias against diagnostics. This is seen at every stage of the process, from the initial questions, through the planning stage where the National Programmes of Care don't appear to have a structure which will accommodate diagnostics input. The structure proposed could lead to a situation where CPAG could be asked to prioritise a highly complex diagnostic about which they may have little knowledge and there will be little to help in the literature. (Anonymous)*

To return to a key issue noted throughout many responses was that of weighting which was that the ***principle of reducing inequality would be hard to operationalise without it being given a higher weighting than these other principles*** (particularly clinical effectiveness and value for money) because these principles inherently created inequality. An example given to illustrate this is HIV treatment:

> *This principle [equality] is particularly relevant to HIV, which disproportionately affects two key minority populations: men who have sex with men and black African communities. HIV is a health inequalities issue and people living with HIV often experience multiple layers of inequality.*
>
> *Principle (iii)c will only be meaningful, however, if the mechanism for prioritisation for such treatments and interventions are built into the proposed process. This has not yet been done. It is not clear how and at what point NHS England may choose to prioritise, for example, a treatment likely to reduce HIV-related health inequalities affecting gay men, over another treatment which may rank more highly on value for money or affordability criteria. The consultation documents do not provide any indication of who will make this judgment - but it is hard to see how such consideration would be made prior to the CPAG stage.*
>
> *From the sequence outlined in point 20, it does not seem possible that a proposal which could have a significant equalities impact would ever be prioritised above a treatment which is the subject of a NICE appraisal. So given a fixed annual budget for specialised services, NAT has serious concerns about how equality benefits could be given appropriate parity in the decision-making process. (National AIDS Trust)*

A particularly common view, especially among those individuals and organisations representing the rare disease community, was that the ***principles and processes would significantly disadvantage treatments for rare diseases***. This relates to the point discussed previously that a separate process for rare diseases was called for by many respondents. Part of the reason that rare diseases would be disadvantaged related to the prioritisation of NICE approved treatments noted already. The related concern was an implicit understanding that an underlying principle applied in commissioning was that money is best spent when it benefits the greatest number of people, which inevitably works against expensive treatments that benefit a small minority of people. This was considered by many respondents to be a key issue for equality. A common view was that:

> *In the context of rare and very rare diseases there is also the risk that such an approach could deny patients with such conditions the range and standard of care offered to patients with more common conditions which would be in contradiction to the principle that 'everybody counts'. (BioIndustry Association)*

This also led some to ***question why the Cancer Drugs Fund was not included*** in the proposed policy which was seen by some to indicate cancer being given greater priority than other conditions such as rare diseases:

> *Excluding the cancer drugs fund and cancer drug evaluation from this consultation and from the commissioning policy process may lead to health inequalities due to an inequitable approach towards establishing the value and funding of treatments and interventions. (Boston Scientific)*

It was felt that issues noted previously relating to wider engagement of patients and public in the process was an equality issue because presently ***certain disadvantaged groups also tend to be under-represented in stakeholder engagement***. It was suggested that NHS England should therefore ensure it consults with:

> *groups who tend to be less well represented in public consultations eg people with learning difficulties, people with cognitive impairment, people with sensory impairment, homeless people, travellers, BME communities and LGBT communities and individuals. Such groups may not have "national bodies" which can represent the views of all. (Anonymous)*

Another specific area where many respondents expressed concerns about equity was mental health. This relates to the comments noted previously about the principle of 'parity of esteem' and again how this links with the currently unavailable scorecard or system of weighting principles. Many respondents felt that the ***processes described were unlikely to achieve 'parity of esteem'***, partly because of the priority given to NICE, but also because of the perceived under-investment in mental health to date which would mean that significant investment was required over and above other prioritisations in order to reach parity before this status can then be maintained. Some respondents suggested however that there was potential within the policy for mental health services to benefit:

> *We would also hope that NHS England will use the ever-increasing data availability on mental health outcomes, and the gap between these and some physical health interventions to justify significant additional investment in specialist mental health services as a key contributor to reducing health inequalities.(Tees, Esk and Wear Valleys NHS Foundation Trust)*

Relating to the call noted previously for an 'implementation stage' which would ensure local implementation of decisions, many respondents were concerned about inequalities arising based on geography. Related to this were comments about the existing ***potential for inequity within specialised services based on geography of certain specialised centres*** and there were calls for equity of access to be taken into greater consideration when designating specialist services:

> *We also recognise that many specialised services are concentrated in a small number of providers in order to ensure effective clinical skills and service infrastructure for the (relatively) small number of patients who access these services. However, we also recognise that this is likely to result in significant inequity of access for patients in different geographical areas. The RCP therefore recommends that NHS England has an effective process for assessing whether this effect occurs. (Royal College of Physicians)*

Specific examples of where travelling long distances for care were particularly problematic and creating particular inequity were Mother and Baby Units and inpatient eating disorder services. Some respondents thought that any long inpatient stay was deemed inappropriate to be at a long distance from a patient's home and support network.

3.5 Service Review Priorities

The survey asked respondents the following:

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.

Responses to this question have been collated into a list of suggestions. Where respondents gave explanations for the suggestion, the points made broadly speaking followed from issues already covered in the preceding analysis of themes. Therefore, to avoid repetition and because most suggestions did not come with a detailed justification, the suggestions are provided in a simple list format below. The suggestions are grouped into services, specific conditions and specific interventions. Because this was a qualitative survey and the full profile of respondents is not known (see Appendix I), the frequency of each suggestion has not been calculated here as it could potentially provide misleading information about the relative popularity and weight given by respondents to each suggestion.

Services
Adult mental health
Child and Adolescent Mental Health Services
Cancer services for young people
Cardiology
Children's services
Community care
Dermatology
Disability services
End of life
Existing services
GP services
Integrated care
Learning disability
Mental health
Midwifery
Neonatal /fetal services
Neurological services
Neuropsychiatry
Obesity services
Opthalmology
Orthopaedics
Pain services
Perinatal mental health
Psychiatry
Renal services
School nursing
Specialised paediatric rheumatology
Specialist nursing
Student services
Talking therapies
Transition services
Urgent care

Specific conditions
Adult epilepsy
Atypical uremic syndrome
Autonomic dysfunction
CFS and related disorders
Cleft lip and palate
Congenital heart disease review (calls for this to be completed urgently)
Connective tissue disease ILD
Dementia
Eating disorders
Functional/somatic symptom disorders
Gender identity
Hemoglobinuria
Hepatitis C
Hypophosphatasia
Infectious diseases
Inherited metabolic disease
Juvenile idiopathic arthritis
Lymphoedema
Lyosomal storage disorder
Male osteoporosis
Multiple sclerosis
Myositis
Neurological conditions
Paediatric epilepsy
Parkinson's disease
Paroxysmal nocturnal hemoglobinuria
Rare diseases
Rare long term conditions
Specialist cancers
Spinal cord injury
Tuberous sclerosis

Specific interventions
Bariatric surgery
Bone marrow transplant
Cardiac resynchronisation therapy
Cochlear implants
Complex rehabilitation
Continuous glucose monitoring
Everolimus for TSC-related SEGA and AMLs
Experimental treatments
Implantable cardiac defibrillators
Molecular diagnostic testing
Neurological rehabilitation
Neurorehabilitation
Newborn screening
Organ donor characterisation
Prevention
Radiotherapy
Rehabilitation
Renal replacement therapy
Self-harm support
Specialised disability equipment
Spinal cord stimulation
Translarna
Transplantation
Vascular surgery
Vimizim

4 Summary of Findings

4.1 Key Findings: Principles

General principles: most respondents said that the principles are sound, fair, appropriate and reasonable and many welcomed the commitment to the principle of transparency. There was, however, a significant concern that the consultation did not include details on whether or how the principles would be weighted which made it difficult to interpret how the four principles would be applied. The principle of consulting with stakeholders and the public was welcome but many thought the voices of the public are not given enough weight, others that patients with direct experience should have greatest weight. The term 'relevant guidance' was thought to require a definition.

Clinical effectiveness: many respondents called for a definition of clinical effectiveness and contested the definition employed by NICE with several examples and explanations given. It was felt that imaging, diagnostics and any interventions in the clinical pathway other than treatments were harder to assess in standard ways for clinical effectiveness, leaving them at a disadvantage. Many thought patient benefit should be an over-riding principle, taking priority over issues of cost. It was also felt that not prioritising treatments that were the only treatment available could prevent innovation and would disadvantage conditions where there was only one treatment.

Equity: Prioritising treatments for rare conditions in the absence of clinical effectiveness data was seen as contradicting the principle of clinical effectiveness and there were calls for further justification for these treatments although representatives of the rare disease community welcomed it. Many called for a more detailed definition of equity along with reference to evidence. Requiring treatments to be offered to all patients in a group was thought to contradict principles of personalised medicine and therefore needed further clarification. Most agreed that assessment of cost and clinical effectiveness should take into account a range of wider benefits. Seeking to advance parity of esteem between mental health and physical health was welcomed but many thought there was a long way to go for this to be achieved and questioned how it would best be implemented.

Cost: Many argued that saving money should not be an over-riding principle although some agreed that value for money was important. Many respondents called for the concept of 'value for money' to be further defined and methodologies to be specified, with many contesting QALY methods. 'Affordability' and 'relevant budget' were both thought to require further detail and some argued that the budget should be flexible to meet needs rather than the budget dictating provision.

Additional principles: Some called for innovation to be prioritised; some called for NHS providers to be the providers of choice; it was felt important to consider the whole pathway and ensure local commissioners and providers are involved; some called for priority to be given to interventions that were preventative or provided early intervention and some also indicated that interventions for children should specifically be prioritised. Patient choice was proposed as an important principle.

4.2 Key Findings: Process

Priority Order: NHS England is legally obliged to fund NICE approved treatments. However, this presented a concern for some respondents for the same reasons that the concept of clinical effectiveness as defined by NICE was contested. It was felt that the prioritisation sequence could be at odds with the principles of equality because of the perceived limitations within NICE. Clarity was called for in distinguishing between third and fourth order interventions.

Five Stages: suggestions were made for how the use of UK Pharmascan could be made more efficient for NHS England scanning purposes. There was some confusion about the separate roles of the Clinical Reference Group, the 'Clinical Appraisal Panel' and the body conducting an independent review of the evidence and clarity was called for. Many emphasised the importance of any group reviewing evidence to have sufficient expertise. Pharmaceutical companies were particularly

concerned that unpublished evidence from manufacturers should be taken into account. Some also suggested that NHS England should not be involved with any aspect of evidence review as this should be left to the expertise of NICE. Some called for NHS England to accept any medicine that had received approval from the European Medicines Agency to avoid duplication. A number of respondents felt that impact analysis occurred too late and should take place earlier in the process.

Decision making: There was disappointment among some respondents that the proposed scorecard was not included as part of the present consultation. It was thought that this development would benefit from an academic approach and some suggested adoption of the former Advisory Group for National Specialised Services (AGNSS) principles.

General points on process: Some commented that it was unclear how the principles had been applied to the process. There were a number of ways in which there could be incompatibility with industry timelines and an alternative recommendation was for a rolling quarterly process. Another alternative process submitted by the Specialised Healthcare Alliance was endorsed by several of its member organisations. Individual Funding Request procedures were criticised and clarification was sought on how the present proposal would fit with this process as well as other interim processes such as the In-Year Service Development process, Commissioning through Evaluation and Early Access to Medicines Scheme. Interim arrangements were requested for decisions still pending.

Additional stages: Although the process was widely described as too complex and likely to lead to delays, a number of additional stages and processes were suggested:

- Pre-scanning stage
- Preliminary evidence review by CRGs
- Risk assessment to review impact on patient safety
- Transition stage for “trialling the process” and “staff training”
- Appeals process (a particularly widespread and strongly felt requirement)
- Implementation stage, particularly to ensure local and regional implementation

Some also called for separate processes to be put in place for decommissioning and reviewing existing services; imaging and diagnostics; and for rare diseases.

4.3 Key Findings: Stakeholder and Public Engagement

Stakeholders in general: Respondents welcomed an emphasis in the process on more extensive stakeholder engagement and consultation. It was widely felt that CRGs need more support and a review of their role and structure; membership of CRGs was thought to require review and clearer terms of reference in order to ensure consistency, adequate representation of all stakeholders and avoidance of conflict of interest. Many called for clearer mechanisms for providing input and views and a number of variations around better website presence and functionality for this were put forward. To improve transparency it was felt that stakeholder involvement needed to be clearly demonstrated and documented throughout the process and that involvement should take place from the very beginning of the process (scanning) and throughout the process including reviewing the evidence, not just at a consultation stage. A number of other proposals were also made on how processes around transparency in general could be developed and/or improved.

Patient and public engagement: It was felt that carers are not currently involved sufficiently in the process and that they should be more involved. Some suggested that views of the general public should be sought as well as views of those who have experienced the illness directly to achieve balance. In particular, there was concern that highly emotive and personal narratives could have undue influence within the process if not moderated against other views. It was suggested by some that if CRGs are appropriately structured and resourced then this was an adequate mechanism but many indicated that better structures for public engagement would be needed to achieve wider representation. The register of interested stakeholders held by CRGs was thought to be too passive a mechanism and various suggestions were put forward for engaging a wider spread of the population.

Some respondents recommended a ‘Compact’ agreement in use in other public sector engagement be adopted by NHS England to provide guidelines for involvement. As with stakeholder involvement generally, it was widely suggested that patient and public involvement needs to be part of the whole process from the very beginning and at every stage. There were calls for patients and public to be involved in development and consultation on the proposed scorecard methodology and also on an appeals stage.

4.4 Key Findings: Reducing Inequalities

Several respondents felt that if followed properly, the principles and processes set out would help to reduce inequalities. However, some queried whether the priority sequencing described in the consultation document would naturally disadvantage some patient groups such as those with rare diseases, mental illness and children.

It was widely argued that the principles and processes would disadvantage treatments for rare diseases and the wish for a separate process was re-iterated; some questioned the equity of cancer drugs having their own process (the Cancer Drugs Fund) and called for equity along these lines for rare diseases (although for some this meant including cancer drugs in the process, for others this was having a separate process for rare diseases also). Issues previously noted around the lack of full representation from various stakeholder, patient and public groups was also thought likely to lead to inequity. Some thought that the processes were unlikely to achieve ‘parity of esteem’ for mental health. On geography and equality, many also took the opportunity to state concerns about some specialised services being hard to access geographically for some populations.

5 Appendix I: Respondent Profile

Excluding duplicates (5), there were 278 responses mostly received electronically from an online survey hosted by the NHS England website with some sent directly by email to NHS England.

A significant proportion of responses (34.5%) were anonymous, but many respondents provided information about what area of healthcare they represented with some representing specific organisations. Specific named organisations providing organisational responses are listed in Appendix II. A small proportion of respondents indicated an organisation that they worked for but it was clear from the data that these were individuals who were *members of an organisation*, rather than responding *on behalf of an organisation* and these were not listed as organisational responses in Appendix II. All responses providing identifying information about the area of healthcare they represented were classified as follows:

AREA OF HEALTHCARE	Count	Percentage
Academic	1	0.4
CCG/Local Authorities	5	1.8
Charities	46	16.5
Commissioners	2	0.7
Expert Group Members (including CRGs)	11	4.0
Healthcare Industry incl Pharmaceutical Companies	38	13.7
NHS Bodies/Trusts	19	6.8
NHS Professionals	13	4.7
Professional Bodies	6	2.2
Service Users/carers/public	43	15.5
Anonymous/no information	96	34.5
Total	278	100

Respondents were not asked explicitly to identify what area of healthcare they represented nor to name or describe the organisation they represented. The information available about respondents was mostly given in response to the final survey question asking respondents to declare any vested interests (see Appendix II). Many respondents without vested interests described their role or organisation here but many also left this blank. It is therefore impossible to infer the extent to which the anonymous responses would fit the same profile as those who did identify themselves. The group of respondents in the 'Anonymous/no information' category are likely to be made up of the categories where vested interests did not need to be declared i.e. all groups except charities and healthcare industry representatives.

Representativeness of Responses

It is important to consider how representative of the wider population of stakeholders the views offered by respondents to this consultation might be by considering the extent to which the respondents represent the greatest possible diversity of views that might exist about the issues the consultation is concerned with. In qualitative research, this is referred to as 'trustworthiness'.

There were some limitations in the consultation method and response pattern. For example, some respondents reported finding the consultation difficult to respond to for a range of reasons including language use. Some respondents felt the consultation may be premature (without a scorecard or standard operating procedures available to consult on in tandem). Also, as noted in Appendix II, some charities (18 out of 46) declared vested interests as did all the healthcare industry respondents which should be taken into consideration.

In spite of these issues, it appears that all respondents felt able to provide their views on the general issues within the consultation document, which suggests that the difficulties experienced in understanding the document did not generally prevent respondents offering their views. Moreover, the responses to this consultation offer good trustworthiness since the response rate was high and a range of different interests were represented including service users, carers and the public, NHS professionals, professional bodies, members of expert reference groups, charities and the healthcare industry. The overall number of responses was high and allowed the analysis to achieve full 'saturation', which means that during the analysis there was a point at which no new ideas or views were emerging from the continued examination of individual responses. This 'saturation' facilitated the development of key findings from the qualitative analysis and provides confidence in the themes arising from the analysis.

6 Appendix II: Named Organisation Responses

Academic
King's College London (KCL) and University College London (UCL) group on Social Values in Health Priority-Setting

Associations and Alliance Organisations
Children's Hospital Association
Federation of Specialist Hospitals
NHS Providers
Specialised Healthcare Alliance
The Association of UK University Hospitals (AUKUH)

CCG/Local Authorities
Gateshead Council Public Health
Leeds City Council and 3 CCGs
NHS Clinical Commissioners
NHS Redditch & Bromsgrove CCG
NHS South Worcestershire CCG
NHS Wakefield CCG
NHS Wyre Forest CCG

Charities
Adult Cochlear Implant Action Group.
Alopecia UK
Anthony Nolan
Aspire response
Association for Glycogen Storage Disease UK
Asthma UK*
Bliss
British Kidney Patient Association*
British Lymphology Society (Operations Manager)
Cancer Research UK
Cancer52*
Cystic Fibrosis Trust*
Dystonia Society
Epilepsy Action*
ERCA
Genetic Alliance UK
Headway
LGBT Foundation
MIND
Motor Neurone Disease Association
Muscular Dystrophy UK*
National AIDS Trust*
National Kidney Federation*
National Rhematoid Arthritis Society*
Niemann-Pick UK *
Parkinsons UK
Primary Immunodeficiency UK*
Reverse Rett
Sarcoma UK*
Sickle Cell Society
Spinal Injuries Association*
Tamba*
Teenage Cancer Trust
Terrence Higgins Trust

The Children's Heart Federation
The Gauchers Association*
The Gender Identity Research and Education Society
The PHG Foundation
The Picker Institute
The Scleroderma Society *
The Society for Mucopolysaccharide Diseases*
Tuberous Sclerosis Association*

Expert Groups
PET CT Clinical Reference Group
Rare Diseases Advisory Group

Healthcare Industry incl Pharmaceutical Companies
AbbVie
Actelion
Alexion Pharmaceuticals
Association of the British Pharmaceutical Industry
AstraZeneca
Baxter International Inc
Bayer Plc
Biogen Idec
Boehringer Ingelheim
Boston Scientific
Bristol-Myers Squibb
Ethical Medicines Industry Group (EMIG)
Genzyme
Gilead Sciences Inc
GSK
Intuitive Surgical employee
Janssen
Johnson & Johnson
MAP BioPharma
Medtronic UK
Merck Serono Limited
MSD
Novartis
NPS Pharmaceuticals Ltd
Ottobock
Pfizer
PTC Therapeutics Limited
Roche
Shire
The Association of British Healthcare Industries (ABHI)
The Medical Technology Group
The National Clinical Homecare Association
UK BioIndustry Association
Vertex
ViiV Healthcare

NHS Bodies/Trusts
Central Manchester University Hospitals NHS Foundation Trust
Great Ormond Street Hospital for Children NHS Foundation Trust
Guys and St Thomas' NHS Foundation Trust
Leeds Teaching Hospitals NHS Trust (Medical Director and Chief Operating Officer)
Organ Donation and Transplantation Directorate, NHS Blood and Transplant
Royal Free London NHS Foundation Trust
Tees, Esk and Wear Valleys NHS Foundation Trust

UK Genetic Testing Network

Professional Bodies
Royal College of Nursing
Royal College of Physicians
Royal College of Psychiatrists
Royal College of Surgeons of England

Scrutiny Bodies
Healthwatch England

Service User Organisations
Birmingham ITB User's and Carer's Group
North East Eating Disorder Action Group (NEEDAG)
PPE Representatives of the Blood and Marrow Transplantation Clinical Reference Group
Public Reference and Advisory Panel (PRAP) at Trafford CCG
Rare Disease Patient Group
Royal College of Surgeons Patient Liaison Group
The National LGB&T Partnership
UK Primary Immune-deficiency Patient Support

Note on Vested Interests

Respondents were asked to "declare any financial or other interests in any specialised services". Specific interests required were:

- Voluntary organisations which 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

  Organisations declaring this type of funding are marked with an '' in the list above*

- Commercial suppliers to the NHS of specialised services

  These organisations are those in the ***Healthcare Industry incl Pharmaceutical Companies*** *list above*

No other organisations declared financial or other vested interests.

7 Appendix III: Acronyms Used in this Report

AGNSS	Advisory Group for National Specialised Services
CCG	Clinical Commissioning Group
CPAG	Clinical Priorities Advisory Group
CRG	Clinical Reference Group
CtE	Commissioning through Evaluation
EMG	European Medicines Group
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HST	Highly Specialised Technology
HTA	Health Technology Assessment
IFR	Individual Funding Request
LHO	London Health Observatory
LTC	Long Term Conditions
NICE	National Institute of Clinical Excellence
NSF	National Service Framework
PoC	Programmes of Care
PPRS	Pharmaceutical Price Regulation Scheme
PPVAG	Patient and Public Voice Assurance Group
QALY	Quality Adjusted Life Years
RCT	Randomised controlled Trial
SIGN	Scottish
STA	Single Technology Appraisal

8 Appendix IV: Specialised Healthcare Alliance proposed alternative process

Executive summary

- NHS England requires a new policy development process for specialised commissioning, which is robust, efficient, transparent and fair.
- A robust process will not be rapid but must be predictable. There should be clear roles for those involved in each part of the process. Programme of Care Boards prioritise proposals for development; Clinical Reference Groups then draft policy documents, seeking broader input; commissioners assess the broader impact of the proposals and then consult the public. NHS England's senior leadership then reaches a decision.
- Implementation should follow swiftly from the completion of the process – delays following Board approval are unjustifiable.
- Given the absence of other funding streams for specialised care, NHS England must develop practical interim access arrangements for patients urgently requiring new therapies while the policy development process is in train.
- Highly specialised services require their own policy development process, led by a single national team, before submission to the Clinical Priorities Advisory Group.

A new policy development process

NHS England's new policy development process needs to be rigorous, fair and transparent, with ample opportunity for key stakeholders and the wider public to feed in their views. A new approach is therefore proposed below. This envisages open, continuous horizon scanning on the part of NHS England, whereby any new policy developments can be listed for future consideration. Annual topic selection by Programme of Care Boards seeks to ensure that proposals with the greatest potential to benefit patients are taken forwards, rather than proposals most vociferously championed by Clinical Reference Groups (CRGs) or others. *Dedicated webpages for each policy in development are planned, to ensure that the public is able to track progress. This would emulate NICE's best practice and address the confusion characteristic of the current process.* Once a topic is selected, CRGs will then be trusted to develop a policy based on the best available evidence. They will be expected to share this draft for input from their registered stakeholders for two weeks. They will then share the draft policy with two fellow CRG Chairs for peer review, helping to ensure the quality of the document without invoking a lengthy external review process. *This means that, when the CRG has finished developing the policy, it will have received input from a range of experts and will be ready for wider commissioner scrutiny.* The Accountable Commissioner then works with colleagues across NHS England to test the service and financial impact of the proposals. The public will then be consulted, usually for a month, for input on the draft policy and NHS England's estimation of its service and financial impact. *This means that, by the time the Programme of Care Board receives the proposed policy, its financial and service impact will have been verified or commented upon by key stakeholders and the public, with feedback from the engagement exercise available for Board members to consider.* The Programme of Care Board then submits the policy proposal to the Clinical Priorities Advisory Group, which considers it against the prioritisation criteria agreed in early 2015. Its recommendation is then published, with a two-week opportunity for final appeals. *This means that, when a CPAG recommendation arrives for final sign off, the Specialised Commissioning Oversight Group will be fully apprised of its strengths, weaknesses and any remaining stakeholder objections.* Finally, the Specialised Commissioning Oversight Group signs off the policy and publishes it on the NHS England website. Implementation is usually required within a month of the Oversight Group meeting.

Policy Development Timeline

1. Horizon scanning
Any potential service developments should be submitted for consideration by NHS England. This process is ongoing. Anyone can submit potential service developments for inclusion at any time on the relevant Clinical Reference Group webpage. CRGs also proactively scan for new topics and NHS England works closely with the ABPI, ABHI and others NHS England needs to be clear about the information required for topics to be selected.
Responsible body: The Accountable Commissioner of the relevant Clinical Reference Group is responsible for overseeing the list. **Decision-making criteria** Before adding a suggestion to the list, the Accountable Commissioner will need to check that:
- The proposal is within the scope of specialised commissioning, as set out in the Manual
- The proposal is not already on the list or wholly covered in an existing service

Publications: An updated topic list to be published every quarter by each Programme of Care. This does not commit NHS England to working on any of the topics listed.
An overarching declaration of requirements should be published to give clarity to all stakeholders on what information is needed by NHS England and when it is needed by, in order to ensure the smooth running of the process.

2. Set annual work plan
NHS England will need to prioritise a manageable number of service developments for work-up within a year. However, flexibility will need to be retained to ensure capacity to develop urgent access policies or to react to new developments, for example those triggered by Individual Funding Requests.
Responsible body: The Programme of Care Board will set its annual work plan, selecting from the topics in its horizon scanning list. In making these decisions, care should be taken to involve a broad range of stakeholders and members of the public. Interested stakeholders could contribute to scoping meetings. **Decision-making criteria** This is the first stage of prioritisation. In the first instance, priority is accorded through the Orders set out in the prioritisation framework.

There should be an appeals route for any proposals not selected within the workplan. This would consider whether or not decisions were taken in line with the published criteria.
Publications: The Programme of Care will publish its annual work plan at the beginning of each financial year. This will also be broken down by CRG and published on the relevant webpages. When a policy is not included in a workplan this should also be clearly detailed on the NHS England website, alongside a clear description of remaining options available.

For those that are selected, every proposal in the workplan should have its own webpage charting its progress through the system, as follows:

3. Policy formation
As part of its annual work plan, the Programme of Care will work with the relevant CRG to develop a policy. **3a)** The CRG develops a draft policy, calling in external expertise as required by the Chair. This draft is shared with registered stakeholders for comments and input over a two-week period. The CRG incorporates comments and shares the draft policy with the Chairs of two other CRGs from the same Programme of Care for a peer review and sense check. **3b)** The Accountable Commissioner then takes up the document and tests its potential financial and service impact. These are put to public consultation, along with the draft policy, usually for a month. The documents are then submitted to the Programme of Care Board for consideration, alongside a summary of consultation submissions and changes made to the documents in the light of these submissions. **Responsible body:** The Clinical Reference Group Chair takes the lead on developing the policy, supported by the Accountable Commissioner. The Accountable Commissioner is then responsible for taking the CRG's draft through financial and service impact assessment and public consultation before taking it to the wider Programme of Care Board. **Decision-making criteria** Decisions are not taken at this stage. Evidence is gathered and assessments are made, with public input.

Publications: Updates will be published on the relevant page on the NHS England website (see above). The draft policy and impact assessments will be published for short public consultation.