SHELFORD GROUP RESPONSE TO NICE AND NHS ENGLAND CONSULTATION

Purpose of document

1. This document responds to the National Institute for Health and Care Excellence (NICE) and NHS England consultation on 'Proposals for changes to the arrangements for evaluating and funding drugs and other health technologies appraised through NICE's technology appraisal and highly specialised technologies programme', published on 13 October 2016.

About the Shelford Group

2. The Shelford Group represents ten of the leading NHS multi-specialty academic healthcare centres in England:

   - Cambridge University Hospitals NHS Foundation Trust
   - Central Manchester University Hospitals NHS Foundation Trust
   - Guy's and St Thomas' NHS Foundation Trust
   - Imperial College Healthcare NHS Trust
   - King's College London Hospital NHS Foundation Trust
   - Newcastle-upon-Tyne Hospitals NHS Foundation Trust
   - Oxford University Hospitals NHS Foundation Trust
   - Sheffield Teaching Hospitals NHS Foundation Trust
   - University College London Hospitals NHS Foundation Trust
   - University Hospitals Birmingham NHS Foundation Trust

3. We have a track record over many years of delivering excellent patient care, clinical research and education. In aggregate, we provide high quality health services worth nearly £10bn p.a., which is equivalent to 10% of the whole NHS England budget and over 13% of all NHS providers. We treat many millions of patients each year across the full spectrum of clinical specialties. About one third of our aggregate income is for specialised services and we provide nearly one quarter of all specialised services commissioned by NHS England. We are national and international hubs of research, education and innovation, providing some of the most complex and specialised healthcare in the world. All of our organisations are NIHR funded Biomedical Research Centres. We believe that we are core stakeholders for this consultation.

Response to the proposals

4. Before responding to the consultation document itself, it is essential to address the overall context in which it is published. It has been well documented that the NHS is in the midst of the most austere decade in its history.[1] [2] [3] [4] In contrast to the long run average of close to 4% p.a. real terms growth, between 2010-2020 NHS funding will grow at barely 1% p.a.[5] Nevertheless, demand for health services has risen far more quickly.

5. Scientific and technological innovation in healthcare often increases costs, as has been the case for specialised services in recent years. For example, NHS England had to invest an additional £190m in 2015 after NICE approved new medicines for the treatment of hepatitis C. Over five years, the national specialised commissioning budget is having to rise at an average of around 5% p.a. to attempt to keep pace with rapid demand growth.[6]

6. The cavernous gap between demand for health services and the funding of providers can only be partially narrowed by increasing and stretching efficiency gains, on top of those already delivered so far this decade. Given the distribution of the public spending settlement, the most challenging years for the NHS in this period of austerity are still to come.[7]

7. NICE was established around the turn of the century to reduce variation in the availability and quality of NHS treatments and care; to end the so-called 'postcode lottery'. For the first decade of its existence, NHS budgets grew faster than the historical average and the task was to make effective medicines and treatments available more quickly and consistently. Patients' expectations have risen rapidly as a result. In the latter part of the current decade, patient expectations will not diminish, but affordability for the health service will be much more constrained.

8. Another central part of the context is Brexit, which will present risks and opportunities.[8] In order for the UK to be increasingly successful as an outward-looking, trading nation, we will need to support our most competitive export sectors, one of which is undoubtedly biomedical science. In line with the final report of the Accelerated Access Review (AAR), we will need to ensure that the NHS continues to be one of the most innovative health systems in the world, providing rapid access to proven medicines and technologies, and attracting the best scientists and industry investment as a research partner.[9]

9. The essential dilemma is how the NHS can continue to meet the high expectations of patients for access to medicines and treatments of proven efficacy and value, and be a health system that embraces innovation and scientific investment, and one which manages the associated cost pressures within limited available resources. This is not an easy balance to achieve. It calls for a pragmatic response to manage down cost pressures in the short term, whilst not overly compromising a longer term strategy of investing in the discovery of, and access to, new medicines and technologies.

10. Within that difficult context, we cautiously support the proposals in the consultation document as a pragmatic and consistent way to manage new funding pressures associated with high cost medicines and technologies from now until the end of the decade. They should help to avoid different decisions on affordability and access in different localities. We believe it should be clear that the proposals apply to commissioning at all levels – from national to regional and local, and for NHS and local government commissioned services – for the sake of consistency and equity of access.

11. However, we also believe that these arrangements should be temporary, until such time as UK economic growth allows the Government to return NHS spending to closer to the historic trend.[10] When affordability is less of a constraint than it will be for the next few years, access to medicines and technologies of proven efficacy should be loosened again, so that patients benefit as soon as possible and so that the NHS can maintain a globally competitive status for innovation and investment in R&D.

12. There are two essential requirements which need further development to make the consultation proposals work most effectively in practice. The first is transparency of costs and the second is engagement with patients and providers.

13. The consultation proposes a fast track approach for new medicines that are expected to have a lower cost impact, below £10,000 per QALY. This is welcomed in principle and consistent with the AAR, which we support fully. However, if there are multiple, lower cost medicines, being made

available through the NHS more quickly, there could be a potentially significant cost impact for providers in aggregate, and those costs need to be well understood.

14. Similarly, medicines and technologies that trigger the proposed 'budget impact threshold' of £20 million per annum will be delayed, and will hopefully be less costly after negotiations with suppliers, but will ultimately increase costs for NHS providers. Furthermore, if the £20m cost threshold is net rather than gross, then there needs to be clarity about how projected savings are costed and by whom. Over-ambitious or unrealistic savings projections in either scale or timeframe could bring a new medicine or technology under the net threshold when in fact the true costs will be higher, especially with the upfront investment costs of introduction. This needs further explanation and transparency of calculation and assessment.

15. All of these costs needs to be made transparent and appropriately reflected in prices through tariff or other specialised commissioning arrangements. This is essential to ensure that the policy aim of managing new cost pressures is in fact being achieved overall, that the impact on individual specialised providers is properly understood and that new costs are reimbursed fairly.

16. We also believe that the proposals should more clearly set out the intention to engage with patients and providers of specialised care. Patient involvement is central to the AAR, which will mean that the development of new medicines and technologies reflect patient needs. Patient involvement has also been a strength of NICE appraisals to date, so we assume this is simply an omission of emphasis in the document.

17. It is essential to work closely with providers of specialised services, for instance in modelling the cost impact of new medicines. The proposals read mainly as a set of arrangements between NICE as the regulator, NHS England as the national payer and manufacturers as the suppliers of new medicines, with little attention given to specialised hospitals as the providers or patients as the consumers. To take an example of why providers should be more involved, if NICE and the manufacturers of a medicine were to under-estimate its cost impact, where would the financial risk fall? Would providers have to absorb the costs, would commissioners have to pay more than they had expected, or would the payment to the manufacturer be capped at the level of cost they estimated?

Specific responses to consultation questions

Q1. Do you agree that NHS England should set a budget impact threshold to signal the need to develop special arrangements for the sustainable introduction of cost-effective new technologies?

Yes, in line with our comments above.

Q2. Do you agree that £20 million is an appropriate level? If not, what level do you think the threshold should be set at and why?

We do not have a view on the specific aggregate threshold, other than that it should be kept closely under review, with providers and patients involved, to ensure an appropriate balance between managing new costs pressures and allowing patients access to new medicines and technologies.

If the threshold is calculated on a net rather than gross basis, it is important to be clear on how potential savings are projected because there could be an incentive to over-estimate either the scale or the timeframe of savings in order to come under the net £20m impact threshold.

It is essential that costs for individual providers are considered, as well as the aggregate costs, because a particular medicine may have a modest cost overall but a major impact on a particular provider of a specialised service. We make the point in our comments above about the importance of transparency of costs both in aggregate and for individual specialised providers.

Q3. Do you agree that NHS England should enter into a dialogue with companies to develop commercial agreements to help manage the budget impact of new technologies recommended by NICE?

Yes, and they should improve their commercial capability accordingly, in line with the PAC recommendations.

Q4. Do you agree that NICE should consider varying the funding requirement for technologies it recommends, for a defined period, in circumstances where NHS England makes a case for doing so, on the grounds that the budget impact of the adoption of a new technology would compromise the allocation of funds across its other statutory responsibilities?

Yes, in line with our comments above.

Q5. Do you consider that the criteria for the fast track process are appropriate? If not, what other criteria do you suggest?

They are appropriate although other criteria may become apparent over time for fast tracking other medicines and technologies, so the criteria should be reviewed at regular intervals.

Q6. Do you agree that NICE should 'fast track' new health technologies with a maximum incremental cost-effectiveness ratio of £10,000 per QALY and whose costs are estimated to fall below the budget impact threshold?

In principle, we support fast tracking of medicines where possible, but the costs should be considered both in aggregate and for individual providers. They should be made transparent and providers should be reimbursed accordingly.

Q7. Do you agree that NHS England should commit to accelerating funding for technologies approved under the fast track process from 90 days to 30 days?

In principle, we are supportive of swift access for fast tracked medicines and technologies. However, we are sceptical about whether it is possible to respond much more quickly than 90 days, and 30 days seems unrealistically fast.

Q11. Do you agree that if the cost per QALY level is exceeded, the technology should be considered through NHS England's specialised commissioning prioritisation process?

Not necessarily. It is clearer for the NHS if NICE is the key point of reference. If NICE does not approve a technology, then it should not be commissioned

Q12. Do you agree that the proposed new arrangements mean that NICE would not need to take budget impact into account in its highly specialised technologies evaluation?

Not necessarily. It would seem prudent also to track budget impact for highly specialised technologies.

Conclusion

18. We believe it is an urgent national priority to return the funding of the NHS to somewhere closer to the long run average, alongside similar increases for social care. The gap between demand for health services, including the most specialised, and the funding available is becoming intolerable. Until the UK economy can bear greater investment in the NHS, a pragmatic response is needed to manage down cost pressures and to prevent a new 'postcode lottery' of access emerging in response to financial constraints.

19. The proposals in the consultation document potentially represent that pragmatic way forward up to 2020. The two important caveats are that the costs of new drugs, both those that are fast-tracked and those that are above the cost impact threshold, should be tracked transparently in aggregate and by provider where necessary. This will ensure that the policy is having the intended effect to reduce new cost pressures and that individual providers are properly reimbursed.

20. In the long run, and in the context of the UK's post-Brexit economy, it will be important that the NHS is properly funded to meet demand, that patients' access to new medicines and technologies is not constrained and that the NHS is able to remain a globally attractive partner for biomedical researchers and the life sciences industry.

Submitted by the Shelford Group on 13 January 2017

End notes

[1] Health Select Committee, *Impact of the Spending Review on Health and Social* Care (July 2016).
[2] The King's Fund, *Deficits in the NHS 2016* (July 2016).
[3] Nuffield Trust, The Health Foundation and The King's Fund, *The Spending Review: what does it mean for health and social care* (December 2015).
[4] The Health Foundation, *A Perfect Storm: an impossible climate for NHS providers' finances?* (March 2016).
[5] Nuffield Trust, The Health Foundation and The King's Fund, *The Autumn Statement: Joint statement on health and social care* (November 2016).
[6] NHS England board paper, 'Strategic Framework for Specialised Services' (26 May 2016).
[7] Nuffield Trust, The Health Foundation and The King's Fund, *The Autumn Statement: Joint statement on health and social care* (November 2016).
[8] The Shelford Group, 'Evidence to the Health Select Committee's inquiry into the impact of Brexit on health and social care' (14 December 2016).
http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/health-committee/brexit-and-health-and-social-care/written/42213.html
[9] *Accelerated Access Review: Final Report* (October 2016).
[10] The Shelford Group, 'Supplementary evidence to House of Lords Select Committee on NHS Long-Term Sustainability (23 November 2016)
http://shelfordgroup.org/library/documents/Supplementary_Written_Evidence_-_House_of_Lords_Committee_on_NHS_Sustainability.2.pdf