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To: All NHS CEs
Local Authority CEs
Local Involvement Network Chairs
Monitor
Independent Reconfiguration Panel

29 July 2010

Gateway reference number: 14543

Dear Colleague,

Service Reconfiguration

My letter of 20 May set out the Secretary of State's policy commitments on service reconfiguration and the introduction of four tests against which current and future reconfiguration processes will need to be assessed. I am writing to provide further information on the application of these tests.

The Secretary of State has identified four key tests for service change, which are designed to build confidence within the service, with patients and communities. The tests were set out in the revised Operating Framework for 2010-11 and require existing and future reconfiguration proposals to demonstrate:

- support from GP commissioners;
- strengthened public and patient engagement;
- clarity on the clinical evidence base; and
- consistency with current and prospective patient choice.

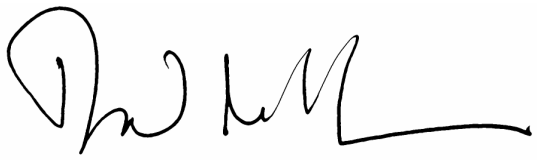
The revised Operating Framework also reaffirmed that the reconfiguration moratorium does not mean that we halt all service redesign. The NHS has always changed and adapted to new technologies, medicines and treatments and must continue to do so. The goal of any change to services must be to ensure patients get the best care possible, delivered to the highest standards in the most effective, efficient and personalised way.

It is vital that the NHS continues to modernise and improve, and to meet the challenges of QIPP, but this must go hand-in-hand with an NHS where improvements are driven by local clinicians, patients and their representatives from the ground up. These tests are designed to ensure this will happen. The recent history of service reconfiguration demonstrates that where change is well planned and well managed, better decisions are made and implementation is more effective.

I am also determined that the new tests do not become overly bureaucratic, and that we avoid a 'one size fits all' approach. The Secretary of State has also made it very clear that GP commissioners will lead local change in the future. With that in mind, I am asking local GP commissioners, in conjunction with PCTs, to lead this process locally and assure themselves, and their SHAs, that proposals pass each of the tests.

I expect a positive and rigorous application of these criteria to both current and future decisions about service change. The following pages outline how this should be taken forward locally.

Yours sincerely,



Sir David Nicholson KCB CBE
NHS Chief Executive

Applying the reconfiguration tests

The Secretary of State has identified four key tests for service change, which are designed to build confidence within the service, with patients and communities. The tests were set out in the revised Operating Framework for 2010-11 and require existing and future reconfiguration proposals to demonstrate:

- support from GP commissioners;
- strengthened public and patient engagement;
- clarity on the clinical evidence base; and
- consistency with current and prospective patient choice.

The application of the four tests should be a thorough and robust process. SHAs will need to work together with local commissioners, GPs, providers (including where appropriate the independent and third sectors), local authorities and Local Involvement Networks to gather and assess the evidence supporting each of the four tests for planned, ongoing and completed service reconfigurations. This guidance outlines two processes, one for schemes underway and a second process for new schemes.

We have chosen not to set specific thresholds for any of the tests, as the process should be locally-led and designed, and needs to allow flexibility given that schemes will be at different points in their lifecycle. In designing their processes, we expect local commissioners to consider the balance of evidence and views, and be able to demonstrate this to their SHA.

In future, new schemes should not proceed to OGC Gateway and NCAT review, and then formal consultation, without a robust assessment being made first of compliance with the four tests. In conducting this assessment, commissioners should apply a 'test of reasonableness' which considers the balance of evidence and stakeholder views in support of a substantial service change. If it is decided, on balance, to go ahead with a scheme then this would continue to follow the established route of OGC/NCAT review, followed by public consultation. OSC powers of referral to the Secretary of State remain unchanged.

Existing reconfiguration schemes subject to the moratorium

We expect that in most cases the local commissioners will lead on gathering the evidence for the four tests. This should be GP-led commissioning organisations such as consortia or, where these are not yet in place, GPs supported by PCTs. As the service is expected to move increasingly towards a GP-led commissioning model, decisions taken now should be consistent with commissioning intentions for the future. As existing consortia structures will vary across the country, and until GP commissioning arrangements are fully established, PCTs will need to provide appropriate support to GPs on applying the four tests.

Local commissioners will need to demonstrate to their SHA that the tests have been applied and met. The exact process to be followed will vary from locality to locality, and will depend on whether the scheme is at an early planning phase, approaching consultation or is post-consultation. However, the tests need to be applied robustly. Where local commissioners are unable to provide evidence that

the tests have been met the SHA should consider halting the proposal and/or seek, where appropriate, further advice from NCAT or the IRP.

To gather evidence, local commissioners should hold or re-open a dialogue with clinicians, local authorities (including Health Overview and Scrutiny Committees) and Local Involvement Networks, understand any concerns over a proposal and work to address these. There is no reason why these dialogues should happen separately for each test, and commissioners may choose to bring together relevant local stakeholders to build a collective view. It is important to ensure that all four tests are handled with equal weight.

In assembling the evidence, local commissioners will need to apply a test of reasonableness and consider, on balance, whether they can demonstrate to their SHAs (and could, if required, demonstrate externally to the IRP) that they have met the tests. Commissioners should consider the overall burden of proof for the service change. Whilst not all issues can always be resolved, commissioners must be able to show that they, and their partners, have taken every reasonable step to address any outstanding issues.

If schemes have yet to proceed to consultation, part of the local resolution process may be to agree that outstanding issues will be tested as part of the consultation process. Where schemes are more advanced, this guidance does not necessarily mean that formal consultation and implementation plans should be reversed. If local stakeholders or individuals have concerns, they will need to provide valid and robust evidence to support their position. This is to avoid schemes which otherwise meet the four tests being delayed by potentially vexatious objections.

SHA assurance of existing schemes subject to the moratorium

SHAs have an important role in overseeing the application of the tests for new and existing schemes. They should assure themselves that local commissioners have developed sound, evidence-based proposals and that (where held) consultations are robust. SHAs should take a rigorous review of the evidence presented, including where commissioners report there are unresolved concerns and how they have sought to address these.

Based on the evidence submitted by their commissioners, SHAs should undertake an assessment of which proposals have successfully demonstrated the tests and should proceed, which require further work and which (if any) should be halted. This initial assessment should have been completed by 31 October 2010.

If SHAs are not satisfied that there is adequate evidence to meet one or more of the tests, it is the responsibility of the commissioner to revisit the scheme and hold further dialogue with local stakeholders to resolve any outstanding issues. Where there are issues that cannot be resolved, the commissioner and SHA will need to make a judgement as to whether the balance of evidence across the four tests supports the proposed reconfiguration. The commissioner or SHAs may want to consider approaching NCAT or the IRP for informal advice in such cases. In all instances local resolution of issues is always preferable.

Where formal consultations have concluded but stakeholders wish to revisit plans in light of the four tests, then local commissioners should attempt to resolve these issues through dialogue or further consultation. It will also be important to ensure that consultees are aware of the changes to the criteria that have been adopted and allow them to provide views on the new tests, if it is found that reconsultation is necessary.

Support from GP commissioners

Local commissioners and consortia should review the current evidence of engagement with GPs and the level of support and consensus for a proposed service change. As GP / practice-based commissioning structures vary across the country, local commissioners will need to take an appropriate view as to how best to gather this evidence, with PCTs supporting this process where required. Commissioners will need to consider the engagement that may need to take place with practices whose patients will be significantly affected by the case for change, inviting views and facilitating a full dialogue where necessary.

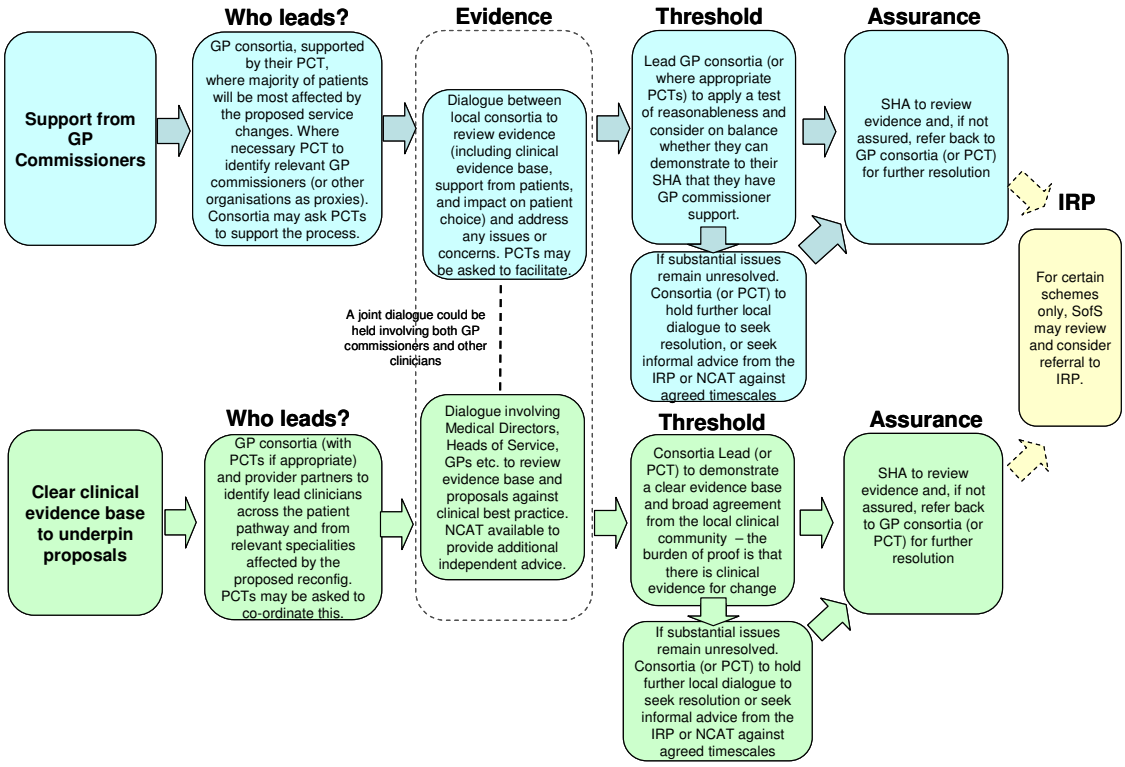
When submitting evidence to the SHA, local commissioners will need to demonstrate the nature of the discussion with consortia or with other appropriate bodies as a proxy where consortia are not available. For example, the commissioner could obtain written sign off from relevant local consortia representatives. If this cannot be obtained, commissioners should revisit and, where possible, address any concerns or amend proposals. The PCT Professional Executive Committee(s) may need to take a view on this as part of any local resolution process.

Clinical Evidence Base

In meeting the clinical evidence test, local commissioners will need to consider both the strength of the clinical evidence and the support from senior clinicians whose services will be affected by the reconfiguration. It will be for commissioners and their provider partners to determine the specific composition of the clinical body to engage, though this should include representatives from across the patient pathway and from different relevant clinical specialties. It is recommended that clinicians should lead in gathering this evidence, considering current services and how they fit with the latest developments in clinical practice, and current and future needs of patients.

If it is decided locally that an independent assessment is required of the clinical evidence base, then the commissioner may choose to invite the National Clinical Advisory Team (NCAT) to provide independent clinical assurance for any proposals – irrespective of whether a consultation has already taken place. This may be especially helpful where schemes have been initiated before the establishment of NCAT in April 2008. Alternatively, the commissioner may choose to engage another independent body of clinicians where this has the support of local clinical stakeholders.

An outline process for applying the GP commissioner and clinical evidence tests is illustrated in the following diagram:



Strengthened Public and Patient Engagement

There is already statutory provision for the engagement of local communities and Local Authority Health Overview and Scrutiny Committees. Section 242 of the National Health Service Act 2006 requires local health organisations to make arrangements in respect of health services, to ensure that users of those services such as the public, patients and staff are involved in the planning, development, consultation and decision making in respect of the proposals. Section 244 sets out the requirement for local health organisations, the SHA, NHS Trusts, NHS Foundation Trusts and as is normally the case, Primary Care Trusts, to request the appropriate Local Authority Health Overview and Scrutiny Committee to review and scrutinise the proposals.

In engaging the public on proposals for service change, commissioners should also continue to take into account relevant equality legislation. The Equality and Human Rights Commission (EHRC) has produced guidance[1], which explains how public authorities can effectively involve all 'protected' equality groups as well as other groups that are less likely to participate.

[1] http://www.equalityhumanrights.com/advice-and-guidance/public-sector-duties/guidance-and-codes-of-practice/general-guidance/

Local commissioners should engage the Local Involvement Networks (LINks) and Health Overview and Scrutiny Committees (HOSCs) to seek their views, and incorporate the outcome into their submission to the SHA. The level of engagement required will depend on the nature of earlier discussions and any support already obtained from these bodies.

Where a formal consultation has not yet taken place, it is expected that the LINk(s) and HOSC(s) will want to review the initial proposal for change. As previously stated, an outcome of this process may be it is agreed that outstanding issues will be tested as part of a formal consultation. Where a consultation has concluded, the commissioner will need to review the consultation outcomes in conjunction with the LINk(s) and HOSC(s). As an integral part of meeting this test, and ensuring openness and transparency with local communities, it is recommended that commissioners (PCTs where appropriate) make public the outcome of any local review.

If a HOSC is not satisfied with the content of a consultation, or that the proposal is in the interests of the health service in its area, it retains the power to refer these issues to the Secretary of State.

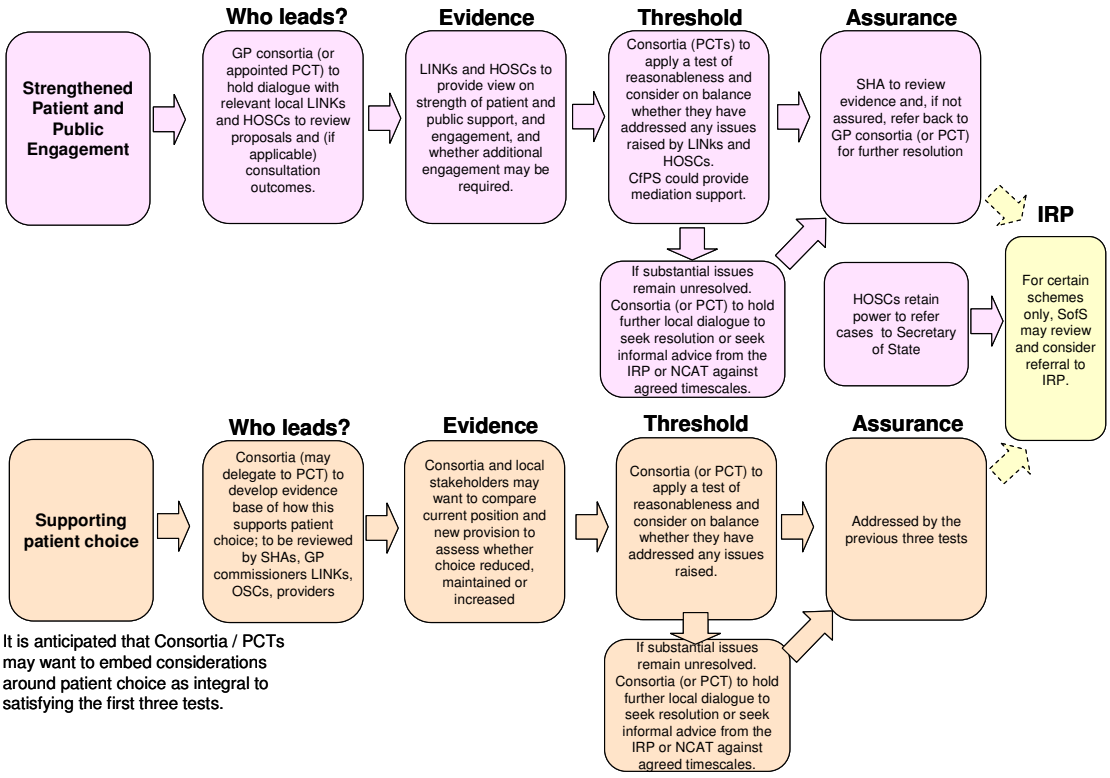
Patient Choice

A central principle underpinning service reconfigurations is that patients should have access to the right treatment, at the right place and at the right time. Services should be locally accessible wherever possible and centralised where necessary. Patient choice and contestability are powerful drivers for improving quality and efficiency in the provision of services.

In this context, local commissioners will need to consider how the proposed service reconfiguration affects choice of provider, setting and intervention; and the choice this presents the patient compared with the current model of provision. Commissioners will need to ensure this consideration is part of any dialogue with local clinicians, LINks and HOSCs. In meeting the choice test, commissioners will want to make a strong case for the quality of proposed services and improvements in the patient experience in their submission.

In addition, all reconfiguration schemes are already subject to the Principles and Rules of Cooperation and Competition (PRCC). Those reconfigurations involving a merger will therefore continue to be required to pass through a formal assessment by the Cooperation and Competition Panel (CCP). Where reconfiguration proposals do not involve a merger, commissioners must seek informal advice from the CCP on the patient choice and competition implications of their reconfiguration plans. This will ensure that potential breaches of PRCC can be identified at an early stage and the CCP can offer advice on the possible range of options open to commissioners

An outline process for applying the public engagement and patient choice tests is illustrated in the following diagram:



Resolving disputes

If local consensus on a scheme cannot be reached, the following three stage resolution process will apply:

1. The commissioner works with local stakeholders to resolve concerns, seeking informal advice from NCAT and/or the IRP where appropriate. If schemes have yet to proceed to consultation, part of the resolution process may be to agree that outstanding issues will be tested as part of the consultation process.
2. If disputes remain in spite of local resolution, the commissioner can refer to the SHA (or the NHS Commissioning Board once established) who may either approve the commissioner's proposal or ask that plans be revisited. The SHA (or NHS CB) may also want to seek informal advice from the IRP, if this has not already been obtained.
3. Where consultations have concluded and objections still remain, the OSC retains the right to refer to the Secretary of State, who may seek the formal advice of the IRP.

Role of the Independent Reconfiguration Panel

The Independent Reconfiguration Panel will retain its formal role so that the Secretary of State for Health can continue to refer cases that have been referred

to him by OSCs. As set out in the revised Operating Framework, where there is insufficient evidence that the four tests have been properly applied, the Secretary of State may, in addition, ask the IRP to review the case and make recommendations.

This guidance does not change the IRP's existing ability to offer informal advice to NHS organisations, local authority overview and scrutiny committees and other interested bodies on the development of local proposals for service change. Further information on this service is available at: www.irpanel.org.uk

Role of the National Clinical Advisory Team

The National Clinical Advisory Team (NCAT) provides an independent pool of clinical experts to support, advise and guide the local NHS through independent clinical assessment of local service reconfiguration proposals. Reconfiguration proposals going to public consultation are subject to clinical assurance provided by NCAT members. In addition, NCAT are also able to provide ongoing clinical advice as schemes develop. Commissioners and SHAs also remain free to seek other clinical advice, as may be appropriate, as proposals mature or are refined.

New and future reconfiguration schemes

The four tests also apply to all future proposals for substantial service change. As GP commissioning structures develop, GP commissioners will want to take a greater role in proposing and leading future service reconfigurations. The tests should be embedded as an integral part of pre-reconfiguration discussions between GP commissioners, PCTs, providers, SHAs, LINks, OSCs and other relevant local stakeholders. This is illustrated in the flowchart overleaf.

This means that, in future, schemes would not proceed to formal OGC and NCAT review, and then formal consultation, without a robust assessment being made first of compliance with the four tests. However, whilst undertaking the work leading to this initial assessment, local commissioners may find it helpful to seek the early view of OGC Gateway and/or NCAT. This may help to optimise efficiencies, further strengthen evidence and proposals, or identify issues that would benefit from further exploration and resolution.

As there may not always be unanimous agreement across the four tests, local commissioners would be expected to apply a 'test of reasonableness' which considers the balance of evidence and stakeholder views in support of a substantial service change. If it is decided, on balance, to go ahead with a scheme then this would continue to follow the established process of OGC and NCAT Review, followed where necessary by formal consultation (which may need to reflect the issues identified in the initial application of the four tests), with OSC scrutiny and, as a last resort, referral to the Secretary of State for Health. It is recommended that commissioners regularly refer back to the evidence against meeting the four tests throughout the life cycle of a reconfiguration, as ongoing engagement should form part of any reconfiguration.

The requirements under Sections 242 and 244 of the National Health Service Act 2006 remain in force and are not affected by this guidance. Earlier best practice

documents published in 2008 - *Leading Local Change*[2] and *Changing for the better*[3] - also provide a further useful reference as to how local proposals should be developed and consulted upon. Furthermore, current statutory and Cabinet Office requirements for formal consultation and the existing OGC Gateway review process are not altered by the introduction of these new tests.

[2] http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_084643.pdf

[3] http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_084672.pdf

Annex A
The revised reconfiguration process for new proposals

This flowchart summarises the full reconfiguration process. Not all service reconfigurations will necessarily go through every stage of this process, for example where it is agreed locally that full public consultation is not required, though the application of the four tests remains an integral and fundamental part of any process.