Clinical Senates role in service change

1. Summary

This paper seeks to do four things:

- clarify the role of clinical senates in service change and how this links to the NHS England assurance process;
- provide guidance on how clinical senates will undertake independent clinical reviews of service changes, including the governance arrangements for reviews;
- outline the support available for clinical senates relating to this work;
- describes how the transition of functions from NCAT to clinical senates will take place and the steps NHS England will take to ensure that clinical senates are prepared to take on these functions.

This document is primarily concerned with the independent advice provided by clinical senates as part of the NHS England service change assurance process. It is acknowledged that clinical senates have other roles (described for example in The Way Forward for Clinical Senates, July 2012 and Operating Framework for Clinical Senates, Nov 2012).

Section 11 makes recommendations including suggested further work.

This paper has been informed by discussion with the national task and finish group members (membership at appendix 6), engagement with Clinical Senate Associate Directors, Senate Managers and wider stakeholders, including the National Clinical Advisory Team.

2. Background

NHS England’s ‘Planning and delivering service changes for patients’ (December 2013) describes the high level framework for service change, a further management document ‘Effective service change: a support and guidance toolkit’ details the assurance process which NHS England applies to service change proposals. These publications have helped to clarify the way in which NHS England has oversight and assurance of service change. The guidance describes a role for clinical senates:

_The aim of clinical assurance is to establish whether the proposed changes are supported by a clear clinical evidence base and will improve the quality of the service provided. The decision to request an external clinical assurance review should follow discussions between the relevant commissioner(s), area teams at the strategic sense check – with input where required from the local clinical senate, who can bring multi-disciplinary strategic advice to the development of proposals._

‘Planning and delivering service changes for patients’, December 2013

NHS England’s process for assuring service change proposals is described in more detail in section 4.
3. Clarifying the role of clinical senates in service change

The National Clinical Advisory Team (NCAT) has previously undertaken independent clinical assurance of service change proposals. The NCAT undertook the following functions:

1. Independent clinical assurance of reconfiguration
2. Early advice
3. Review and investigation of services (e.g. issues of clinical safety)
4. Evidence collection
5. Post-hoc advocacy

Of the five NCAT functions it is intended that function 1, and in some instances function 2, will transfer to clinical senates. The responsibility for investigation of issues of clinical safety (function 3) lies with other bodies. Evidence collection (function 4) is undertaken by a range of organisations including NICE, Royal Colleges and NHS Evidence. Post-hoc advocacy (function 5) isn’t a function for clinical senates to undertake, any advocacy requirements would be considered by NHS England as part of its broader assurance process. In transferring these functions the methodology for exercising each function should be considered and improvements made where appropriate.

Clinical senates are independent non-statutory advisory bodies hosted by NHS England. Each clinical senate consists of a Senate Council and wider Assembly. They are comprised of a core Clinical Senate Council and a wider Clinical Senate Assembly or Forum. The Clinical Senate Assembly is a diverse multi-professional forum providing the Council with ready access to experts from a broad range of health and care professions. The Clinical Senate Council is a small multi-professional steering group. This group co-ordinates and manages the Senate’s business. It is responsible for the provision of advice working with the broader Senate Assembly.

The future role of clinical senates in service change can be described as follows:

1) Early clinical advice to commissioners to help inform the development of proposals
   - Strategic clinical advice to commissioners on relevant clinical guidance/ best practice
   - Advice to support commissioners in developing their case for change, options appraisal and proposed clinical models
2) Independent clinical advice as part of the NHS England service change assurance process
   - Independent clinical advice in the form of a formal report which will be considered as part of the NHS England assurance process for service change proposals.

For proposals within their field of clinical expertise, Strategic Clinical Networks will be best placed to offer advice to commissioners to help shape the development of proposals (element 1 above). For proposals relating to clinical specialties outside of the SCNs remit or wider system changes, SCNs may be able to cooperate to offer advice, the clinical senate may undertake this role or signpost commissioner to other sources of appropriate specialist advice.

If clinical senates decide to offer advice to commissioners to help inform the development of proposals (element 1) they need to be mindful that at a later point they may be asked to offer independent clinical advice as part of the NHS England assurance process (element 2) and the potential conflict of interest that may arise as a result. Transparency will be crucial in all the dealings a clinical senate has with a set of service change proposals.
4. Assurance of service change proposals

Service change assurance exists to give confidence to patients, staff and the public that proposals are well thought through, have taken on board their views and will deliver real benefits. The process supports change proposals through rigorous quality assurance of proposals to mitigate the risk of successful challenge through Judicial Review or referral of proposals to the Secretary of State.

NHS England’s service change assurance process is described in ‘Effective service change: a support and guidance toolkit’ (awaiting publication). The document describes a two stage process applied proportionately to the scale of the service change proposals under consideration. The process is based on the Government’s ‘Four Tests for Service Change’ as well as a range of best practice checks examining all aspects of the proposal (including clinical quality and strategic fit, finance, workforce, activity, programme management arrangements, travel impact, resilience, communications and engagement and use of information technology).

The advice provided by clinical senates is part of the broader assurance process and is considered alongside assurance of the other aspects of a service change proposal. Other external sources of advice, for example the Health Gateway Team review of programme management arrangements, are also considered as part of the same single NHS England assurance process.

At the heart of the NHS England assurance process are the ‘four tests for service change’ which are in the Government’s Mandate to NHS England. One of the four mandatory tests is that a clear clinical evidence base should underpin proposals. In addition to the four tests the NHS England assurance toolkit also identifies a range of ‘best practice checks’ for service change proposals, these include:

- Clear articulation of patient and quality benefits
- The clinical case fits with national best practice
- An options appraisal includes consideration of a network approach, cooperation and collaboration with other sites and / or organisations

Clinical Senates will be requested to review a service change proposal against the appropriate key test (clinical evidence base) and the best practice checks that relate to clinical quality, alongside any bespoke requirements for an individual proposal. Clinical senates will not be expected to advise on issues that will be picked up elsewhere in the assurance process (e.g. patient engagement, GP support or the approach to consultation). The terms of reference for each review will need to be agreed with the Clinical Senate by the lead commissioner.

The level of assurance required for a particular service change proposal will be agreed by NHS England and the lead commissioner on a case by case basis. Larger scale schemes carrying higher risks will require a greater level of assurance in most instances than smaller scale schemes. The commissioner will provide documentary evidence to NHS England against the key tests and a proportionate range of the best practice tests. Where it is agreed to be proportionate to the scale of the proposal change the lead commissioner will request a clinical senate provide independent advice against the clinical key test and the appropriate selection of best practice checks. The clinical senate’s advice will be considered as part of the NHS England assurance process, a diagram of which is at appendix 2.
5. **Undertaking an independent clinical review of service change proposals**

Clinical senates will be requested to provide independent clinical advice by the lead commissioner proposing the service change. Clinical senates will need to agree terms of reference for each review with the lead commissioner, as a minimum this will include reviewing the clinical evidence base underpinning proposals (one of the Government’s ‘four tests for service change’) so that the review meets NHS England’s requirements for the assurance process. This paper proposes drawing up standard terms of reference for independent clinical reviews that can be added to in light of local requirements.

A formal report containing clinical senate advice will be returned to the commissioner who will share it with NHS England as part of their assurance evidence.

It is not intended that a Clinical Senate Council or Assembly undertakes the review itself. The Clinical Senate will need to establish a team of independent clinical experts to undertake the review. The clinical senate (through its Council) will be responsible for the review being carried out by an appropriate review team thought this will not necessarily consist entirely of Clinical Senate members. The review team will be formed by professionals with relevant experience of the clinical issues under consideration; this might include members with experience in the following sectors: primary care; public health; community and social care; secondary care; and tertiary care.

The independent review team may have members from within the Clinical Senate but may also invite other relevant topic experts, for example other clinical specialists, SCN members, members of other Clinical Senates, and/or other credible reviewers with relevant clinical expertise.

The team will undertake their review through analysis of key documentation (to be provided by the commissioner) followed by discussions with key figures associated with the proposals (this might include: the senior responsible owner; medical director; chief nurse lead clinicians; CCG clinical lead; social care staff; and GPs). The review team should agree their approach with the Clinical Senate Council.

The independent review team would be created by, and report to the Clinical Senate Council. The Council has responsibility for the review and should approve the membership of the review team, terms of reference for the review and the final report.

Establishing bespoke independent clinical review teams will enable any potential conflicts of interest to be managed (by excluding conflicted individuals from the review team); the clinical Senate Council overview role helps to ensure consistency between review teams (which are likely to have different members between reviews).

This review process is described in a flow chart at appendix 4.

6. **Governance and accountability arrangements**

Once the terms of reference and timescale for an independent clinical review of service change proposals have been agreed between the clinical senate and the lead commissioner of service change proposals as part of the NHS England assurance process, the Clinical Senate then has responsibility for establishing an independent review team and managing the review process.
The output of the process should be an agreed report that will be considered formal advice by NHS England as part of the assurance process for service change proposals. The assumption should be that clinical senate reports will be placed in the public domain at the conclusion of the NHS England assurance process.

7. Support for Clinical Senates in undertaking reviews

Clinical senates’ credibility will be reinforced by offering consistently high quality advice, presented in independent clinical review reports and supported by clear references to the appropriate evidence base, adding value for all organisations involved in the service change process.

To support clinical senates to achieve these aims it is proposed to develop common supporting documents including guidance on undertaking the clinical review process (to include: business standards; how and when clinical senates might offer advice to the assurance process; draft terms of reference for an independent clinical review team and principles for managing real or perceived conflicts of interest) and a suggested structure for an independent clinical review report.

These products are intended to help ensure consistency between clinical senates whilst remaining flexible enough to be tailored for local use.

NHS England’s area and regional teams sharing information on anticipated future service changes will help clinical senates to determine the likely demand for independent clinical reviews of proposals. NHS England’s Regional Team service change leads can ensure these relationships are established and maintained.

8. Resources

Additional resources will not be available above and beyond existing clinical senate budgets. The level of managerial support and budget for clinical senates far exceeds that of the National Clinical Advisory Team, although it is recognised that clinical senates undertake a wider range of roles.

Further consideration should be given to the practicalities of how clinical senates might collaborate to discharge their functions relating to service change, this may reduce duplication of effort and offer resource savings through economies of scale.

The national network of Associate Directors of SCNs and Senates and Senate Managers has suggested they would be willing to undertake further work to examine the potential for shared working arrangements across clinical senate boundaries. The scope of this work should consider (but not be limited to) the potential for each of the following:

- shared lists of appropriately skilled and willing experts to participate in independent reviews;
- a common repository for clinical evidence for clinical senates and review teams to call upon;
- shared administration for the organisation and coordination of reviews and report writing; and
- host arrangement to coordinate reviews across clinical senate boundaries or support arrangements between clinical senates.
9. **Transition from NCAT to Clinical Senates**

The National Clinical Advisory Team has indicated they will not be taking on further work beyond 1 April 2014 when their funding ceases.

The transition of the clinical assurance function from the National Clinical Advisory Team to Clinical Senates needs to ensure there is continuity in the provision of clinical advice to the service change assurance process, make the most of the NCAT’s learning building on their experience and offer a handover of responsibilities on a timetable that is sensitive to local requirements and development needs.

Clinical Senates will need to have certain elements in place in order to take on the proposed transfer of functions from the NCAT. The following checklist is intended for clinical senates so they can self-assess their state of preparedness and identify development needs.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>In place</th>
<th>Plans in place (inc. dates)</th>
<th>Not identified / no plans in place</th>
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<tbody>
<tr>
<td>Chair appointed</td>
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<tr>
<td>Council membership recruited and meeting</td>
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<td>Clinical assembly established</td>
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<td>Lay representative(s) on Senate Council</td>
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<td>Agreed transparent decision making process</td>
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<td>Agreed conflict of interest policy</td>
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<tr>
<td>Agreed terms of reference agreed</td>
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<td>Declaration of interests</td>
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<tr>
<td>Administrative support</td>
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<tr>
<td>Capacity to manage review and produce reports</td>
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This checklist should help Clinical Senates to undertake an assessment of their ability to undertake the functions described in this paper. Any areas identified by Clinical Senates as not having plans in place should be the subject of further attention as a matter of urgency. Regional Medical Directors will request this information, including a timetable for any developmental work to assure that appropriate plans are in place for a smooth transition of functions to Clinical Senates.

NHS England has oversight of forthcoming service change proposals which will indicate likely future requirements for independent clinical review in each clinical senate’s locality. This will determine the point by which an individual senate will need to be fully able to undertake the advisory role described in this paper and inform their planning and resourcing decisions. This analysis should be undertaken by each clinical senate as soon as possible.

If there are clinical senates that will be required to undertake independent clinical review before it is deemed that they are properly prepared for this transfer of functions a pragmatic solution will need to be brokered by the regional Medical Director in discussion with the Clinical Senate Chair. This might for example be the regional Medical Director asking another senate to provide the advice to the assurance process. The expectation will be that all clinical senates are fully able to undertake the functions described in this paper by September 2014.
Retaining the skills and experience from the National Clinical Advisory Team is important as they have undertaken 123 reviews over 7 years, developed a reputation for providing credible independent clinical advice and have a pool of experienced reviewers. The following actions are proposed to build on the NCAT legacy, whilst also taking the opportunity to examine how the approach to providing independent clinical advice for service change assurance can be further developed to suit the requirements of the current system:

- Dr Chris Clough, Chair of the National Clinical Advisory Team, be invited to take on a national advisory role to Clinical Senates for 6 months, it is suggested that this include a focus on the development and training of potential independent review team members;
- The NCAT are asked to confirm to the appropriate clinical senate if they will have any work outstanding at 1 April so the clinical senate can ensure continuity of support to local service change proposals;
- The existing pool of NCAT reviewers to be shared with clinical senates with the suggestion that they review the lists and consider if they might wish to invite these individuals to participate in Clinical Senate work, including as potential members of independent review teams;
- NCAT terms of reference for reviews are one of the documents used to inform the Clinical Senate common terms of reference for undertaking an independent clinical review; and
- Existing NCAT documents relating to maternity services and urgent and emergency care form part of the national evidence base to be called upon by Clinical Senates when undertaking reviews of proposals that include changes to these services.

10. Issues

The following issues have been identified in the course of this work.

Remuneration would not normally be offered for participation in an independent clinical review team. This is in line with previous NCAT practice and current clinical senate ways of working. In some instances travel and expenses may be covered for independent review team members but this will be for agreement between review team members and clinical senates. Exceptional cases will require local decisions.

Patient representatives on independent review groups are generally not recommended as the review team remit is focused exclusively on offering independent clinical advice. Considerations of the impact of proposals on patients, carers and the public will be examined as part of the NHS England assurance process, as will the approach taken to public and patient engagement in the development of service change proposals. Clinical senate councils may also include lay representatives who will have oversight and sign off of the independent review reports.

In the event of a clinical senate advice being challenged NHS England will oversee any response. Advice is provided as part of the broader NHS England service change assurance process and as such all communications, legal and any other support will be coordinated by NHS England, clinical senates are not expected to put their own arrangements in place.
11. Recommendations / next steps

This paper represents the suggested approach as agreed by the task and finish group. It is recommended that this be considered for adoption by NHS England.

The following are recommended as next steps to support the approach described:

- The task and finish group, working with Associate Directors for SCNs and Clinical Senates and Clinical Senate Managers will oversee the development of common products for use by Clinical Senates as described in section 7.
- Associate Directors for SCNs and Clinical Senates and Clinical Senate Managers are requested to examine the potential for shared working and proposed models (as described in section 8).
- NHS England’s Regional Team service change leads ensure that details of forthcoming service change proposals are shared regularly with clinical senates.
- Regional Medical Directors request that clinical senates complete the self-assessment checklist and provide assurance of their preparedness to undertake the roles described (including plans and timescales to address any identified developmental needs).
- Clinical Senates (with support from NHS England Area and Regional Teams) examine the forthcoming service change proposals pipeline and assess the likely requirement for independent clinical assurance against their self-assessed preparedness to undertake this function. Any issues are identified and immediately flagged to Regional Medical Directors. The expectation will be that all clinical senates are fully able to undertake this function by September 2014.
- The NCAT are asked to confirm to the appropriate local clinical senates what, if any, work they will still have outstanding at 1 April.
- Chris Clough be formally invited to take up an advisory and support role for a 6 month period, with a particular focus on development support for potential independent clinical reviewers, and that this will be funded from existing clinical senate resources.
- Clinical Senates are provided with details of current NCAT reviewers to invite these individuals to participate in Clinical Senate work, including as potential members of independent review teams.
- ‘Effective service change: a support and guidance toolkit’ is updated to take account of the approach to independent clinical advice described in this paper. Consideration should also be given to updating references in ‘Planning and delivering service changes for patients’ published December 2013.
Appendices

Appendix 1. Planning and delivering service change for patient (December, 2013),

A clear clinical evidence base test (page 28)

The objective of this test is to ensure that service change proposals are underpinned by a clear clinical evidence and align with up to date clinical guidelines and best practice.

CCGs (and NHS England for directly commissioned services) should oversee development of the clinical case for change, ensuring it aligns with the best available evidence, and has considered relevant innovations and technological improvements, that could deliver further benefits for patients. The Medical Directors and Heads of Clinical Service of any provider organisations involved in the reconfiguration can also help build the clinical evidence base, providing this does not lead to any conflicts of interest in cases of a competitive tendering exercise.

In many cases, there will be a range of options, and service change proposals should set out clearly the clinical benefits and evidence of each option. Where the merits between different options are finely balanced, clinical leaders should make a reasoned judgement how the weight of clinical evidence supports a particular option. It is good practice to describe how that judgement has been arrived in any subsequent public engagement, so that patients and the public can see the development of options has been rigorous, open and transparent.

It is important also that front-line clinicians affected by the proposed changes are engaged, and commissioners should work towards achieving a clinical consensus on the proposal. Doctors, nurses and other healthcare professionals can be powerful advocates, and have an important role to play in communicating the change to the wider community.

Where there are different clinical perspectives on how services could be improved, these should preferably be resolved through the development and refinement of the proposal. It is neither in the interests of patients nor the reputation of local health services, if any differences of clinical opinion over a proposed change become a matter of public dispute.

Assessment against this test should be overseen by an appropriate clinical lead (either within the CCG or committee subject to any Constitutional or collaborative arrangements already in place), or lead Area Team in the case of services directly commissioned by NHS England. This clinical lead should engage other specialists as necessary but, where possible, should include views from senior clinicians not directly connected with the services under review – as this brings a level of independence to the assessment process.

For complex, multi-disciplinary and large scale change, commissioners should consider approaching the local clinical senate for strategic advice. The National Clinical Advisory Team (NCAT) can also provide an external expert clinical perspective on proposed service changes, and this is described further in the section on Assurance.

Where a proposal concerns integration across the NHS, social services or public health, the relevant local authority directors of social services (adult social services and children’s social services) and directors of public health should be involved in the process, and able to contribute to and evaluate the case for change.
Appendix 2. The draft NHS England service change assurance process

The assurance process

Alignment established between CCG and/or NHS England initiated change proposals

Discuss case for change, early risk assessment, organisational roles, early stakeholder and public engagement, business case and timetable.

Agree level of NHS England assurance required and the NHS England decision making process (proportionate stage 2 assurance arrangements), including use of external assurance (e.g. Senate, Gateway, NCAT).

Four tests applied and proportionate assurance against the best practice checks. Independent assurances (e.g. from Clinical Senates, NCAT and/or Gateway Team) also inform NHS England Panel.

The appropriate decision making forum will be decided on a case by case basis (in line with ongoing wider governance discussions).

Scheme placed on AT and RT monthly reconfiguration tracker grid. (RT, AT and NSC agree roles in process).

NHS England assurance stage 1 strategic sense check

Further development of proposals

Full options appraisal and impact assessment

Clinical Leadership

Business case development (finance, workforce, activity, choice)

NHS England assurance stage 2 Assurance checkpoint (may include NHS England Panel)

Assurance recommendation

NHS England decision making forum

Area Regional National

Assurance decision communicated to commissioner(s)

Progress to public consultation

Agree proportionate on-going NHS England oversight arrangements
Appendix 3. The independent clinical review process: a worked example

1. NHS England agrees level of assurance required with lead commissioner (at stage 1 of NHS England assurance process)
2. Lead commissioner requests clinical senate advice as part of assurance process. Clinical senate and lead commissioner agree terms of reference for independent clinical review
3. Clinical senate establishes independent review team and appoints chair of review
4. Lead commissioner provides key documents to independent review team and supports other review requirements
5. Review undertaken and draft report sent to Clinical Senate Council
6. Clinical Senate Council agrees final report and returns to lead commissioner
7. Report submitted by lead commissioner as part of NHS England’s assurance process.
Appendix 4. The Four Tests for Service Change

Government’s Mandate to NHS England, November 2013, page 14, para 3.4

*Where local clinicians are proposing significant change to services, we want to see better informed local decision-making about services, in which the public are fully consulted and involved. NHS England’s objective is to ensure that proposed changes meet four tests: (i) strong public and patient engagement; ii) consistency with current and prospective need for patient choice; iii) a clear clinical evidence base; and iv) support for proposals from clinical commissioners.*


Appendix 5. References and key documents

- Effective service change: a support and guidance toolkit, unpublished

Appendix 6. Members of the task and finish group

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<tr>
<th>Dir</th>
<th>Name</th>
<th>Role</th>
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<tr>
<td>Medical</td>
<td>David Levy</td>
<td>MD, Mids and East</td>
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<tr>
<td></td>
<td>Damien Riley</td>
<td>MD, North</td>
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<td></td>
<td>Nigel Acheson</td>
<td>MD South</td>
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<td></td>
<td>Andy Mitchell</td>
<td>MD, London (represented by Sue Dutch)</td>
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<td></td>
<td>Cathy Hassel</td>
<td>Senior Manager, NSC</td>
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<td>Ops</td>
<td>Tim Barton</td>
<td>North</td>
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<td>Lorraine Foley</td>
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<td>Policy</td>
<td>Ashley Moore</td>
<td>NSC policy lead</td>
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<td>Jo Poole</td>
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<td>Nigel Beasley</td>
<td>Senate Chair (East Mids)</td>
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<td></td>
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<tr>
<td>NCAT</td>
<td>Chris Clough</td>
<td>Chair, NCAT</td>
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