NHS England

Clinical Senate Review Process

Guidance Notes

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CLINICAL SENATE REVIEW PROCESS: GUIDANCE NOTES

Purpose of this document

This document provides guidance about the role of Clinical Senates in providing clinical advice to inform NHS England's service change assurance process. The document includes a number of templates to be used by Clinical Senates to provide a consistent approach to terms of reference, methodology and reporting of clinical reviews.

This document provides information for:

- NHS England
- Organisations or bodies intending or required to undertake the NHS England service change assurance process
- Clinical Senates: Council, Assembly / forum members, Chairs, Senate Managers and Associate Directors
- Clinical review team members

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1) Context

The NHS has a responsibility to ensure that services are high quality, sustainable and provide value for money to the taxpayer. The NHS Constitution commits us to putting people at the heart of everything we do. Our actions should be based on the understanding that the NHS puts people first. This means we will commission, design and deliver care around the needs and choices of patients, informed by patient insight and engagement.

The basis of any major service change or reconfiguration must be that the change will improve the quality of care, that it is clinically-led and based on a clear clinical evidence base. Service change is often highly complex and attracts high levels of public interest. It is therefore important that schemes are appropriately assured, so that communities can be reassured schemes are high quality, align with best practice and will deliver the benefits expected.

NHS England has a role to support and assure the development of proposals and the case for change by commissioners. The principles of the assurance are that it should be robust, consistent and supportive. At the heart of the NHS England assurance process for service change are the four tests from the Government's Mandate to NHS England[1]. The four tests, intended to apply in all cases of major NHS service change during normal stable operations, are:

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.

In addition to these four tests, the NHS England assurance toolkit[2] also identifies a range of best practice checks for service change proposals, these include:

i. clear articulation of patient and quality benefits

[1] Planning and delivering service changes for patients, NHS England December 2013 http://www.england.nhs.uk/wp-content/uploads/2013/12/plan-del-serv-chge1.pdf

[2] Effective Service Change: a support and guidance toolkit, NHS England, awaiting publication

ii. the clinical case fits with national best practice and clinical sustainability, and

iii. an options appraisal includes consideration of a network approach, cooperation and collaboration with other sites and / or organisations.

As part of the NHS England assurance process, 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.

2) Business standards and receiving requests for clinical review

Clinical Senates will be requested to provide clinical advice on a service change proposal as part of the formal NHS England service change assurance process (Figure A. below provides the NHS England assurance process).

This request to provide advice might come from the commissioner leading the proposal or a regional or area team of NHS England (from now on these will be referred to as the sponsoring organisation). This request will be referred to as the Clinical Review.

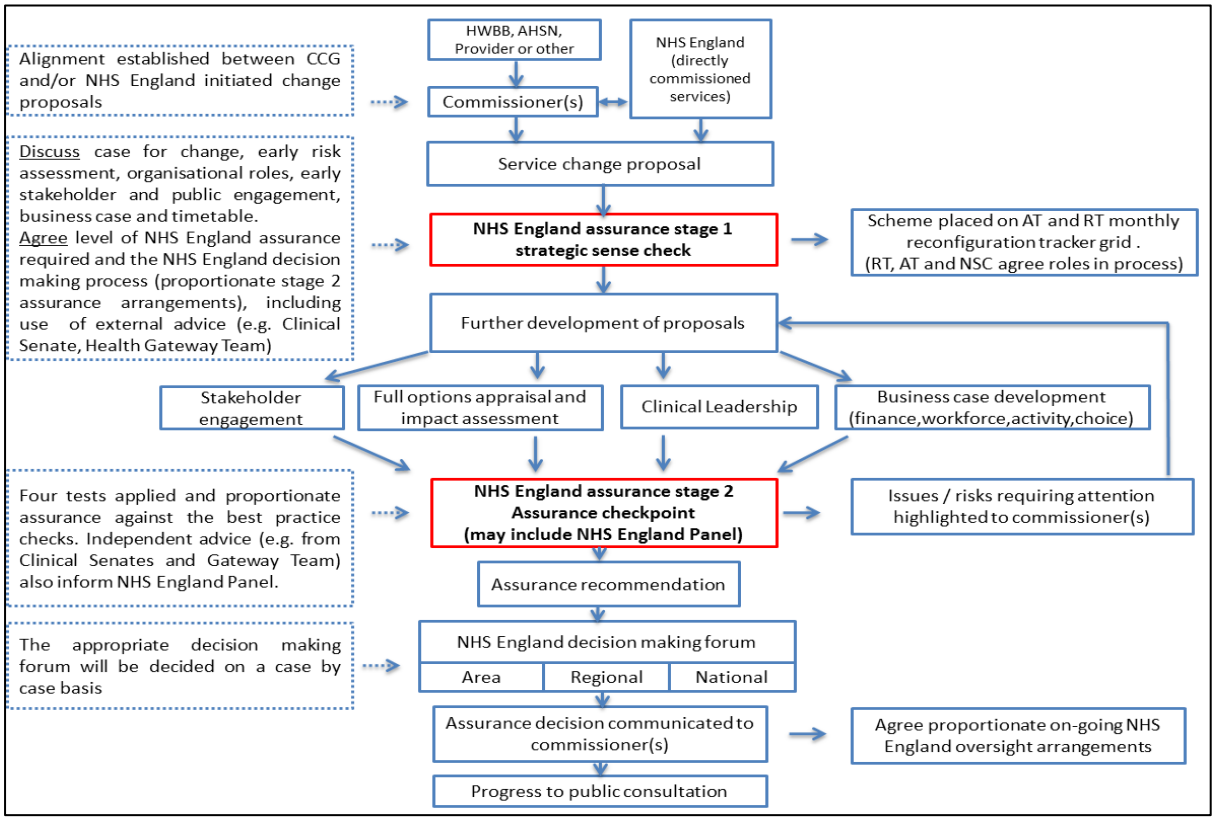


Figure A: NHS England service change assurance process

In order to provide a common approach to responding and proceeding with requests for a clinical review, this paper provides the minimum level of business standards to be applied to clinical reviews that are part of the NHS England assurance process for service change. This paper provides some guidance, an outline of the process to be applied and some outline templates for use; it is also expected that common language will apply across all reviews (i.e. clinical review team, sponsoring organisation). These outline templates are provided as a basis to ensure the clinical review covers the essential elements required by the NHS England assurance process and there that is a consistency of business standards across all reviews and all clinical senates. However, it may be necessary to adapt these in order to accommodate local requirements or agreements. Similarly, the size, nature and complexity of the review will determine the detail and business standards of each clinical review. Clinical senates would also expect to personalise the templates with their own logo and branding.

3) Clinical review: terms of reference

Clinical senate council will need to agree terms of reference for each review with the sponsoring organisation. As a minimum this will include reviewing the clinical evidence base underpinning proposals (one of the Government's four tests for service change). An outline terms of reference for use by clinical senates undertaking clinical reviews as part of NHS England service change assurance process is attached at Appendix i.

The terms of reference must detail the scope of the clinical review, its timeline, methodology and communication plan. This will include all the information that the sponsoring organisation will need to provide to NHS England as part of the assurance process. These requirements will have been part of the strategic sense check discussions between commissioner and NHS England at stage one of the assurance process.

4) Clinical review timeline

The indicative timetable for the review should be agreed at an early stage, ensuring that the review report is finalised in time to inform the NHS England assurance checkpoint. The detailed timetable should be agreed between the sponsoring organisation and the clinical senate, and included in the terms of reference.

In drawing up a realistic timeline, clinical senate and the sponsoring organisation will need to consider a number of principles:

i. Timescales agreed should be clear and must be reasonable to ensure credible clinical input and advice. Ideally the request should be received at least three months in advance of the anticipated clinical review start date. The indicative timetable for a review should be confirmed at an early stage, to ensure that the review report is finalised in time to inform the NHS England assurance checkpoint. The detailed timetable for a review should be agreed between the sponsoring organisation and the clinical senate and included in the terms of reference.

ii. The actual timeline will be dependent upon the size, nature, complexity and dependencies of the clinical review

iii. The timeline should take account of the need to pull together a credible team i.e. a minimum six week notice period may be required to release clinicians from clinical activity

iv. The time required for the sponsoring organisation to bring together the necessary information and evidence to ensure the clinical review team is fully informed (it may be appropriate to confirm the timeline once this stage has been completed)

v. The time required to inform the clinical review team, explore the issues and prepare for interviews, meetings etc.

vi. The expected time and duration of interviews, meetings etc and follow up review and team discussion

vii. Time for report writing

viii. The timeline should include a date for

a. draft report to the sponsoring organisation for factual accuracy (only)

b. the date the sponsoring organisation should respond to the clinical review team by
c. the council meeting for formal endorsement of advice and
d. submission of the final report to the sponsoring organisation

ix. The timeline should include dates and arrangements for publication and dissemination of the information

5) Clinical review team members

Clinical senate will need to establish the team of clinical experts to undertake the review. This multi-professional group will undertake the review and write the report. The size of the clinical review team should be relative and proportionate to the size, nature and complexity of the topic and also the available expertise.

Clinical senate council will appoint an experienced and neutral lead member or chair (terminology to be determined by respective clinical senate). Membership of the clinical review team will be formed by professionals with relevant experience or understanding of the clinical issues under consideration. Clinical review teams should always include an appropriate number of citizen representatives.

The clinical review team is likely to include members from within its own clinical senate but may also include members of other clinical senates, or other invited relevant topic experts. For example, clinical specialists (who may, or may not, come from outside the senate geographical area) and strategic clinical network members.

The team will not include any individuals who will be, or have been, involved in any other part of the NHS England assurance process for this service change proposal.

A suggested membership is available in the Terms of Reference template (appendix i below).

Responsibility for composition of the clinical review team will lie with the clinical senate council. This will be shared with the sponsoring organisation prior to the commencement of the review.

All clinical review team members will be required to sign a Declaration of Conflict of Interest (see section 6 below and Appendix ii) and a confidentiality agreement (Appendix iii). Their names and affiliations will be published in the clinical senate review report.

If a potential team member declares a conflict of interest, this may not automatically exclude them from the team. Section 6 below offers ways to deal with conflicts of interest and Appendix ii provides further detail of the types of interest.

6) Conflicts of interest and loyalty

All clinical review team members will work according to the conflict of interest policy of the clinical senate for which they are undertaking the review.

A conflict of interest can be defined as any situation in which a member's responsibilities or interests, professional or personal, may, or may appear, to affect the impartiality of the clinical senate's advice. That conflict could be direct i.e. applies to themselves or indirect applies to someone or something (body, organisation) known to them or with who they have a relationship. Clinical senates should have policies in place to ensure that actual or potential conflicts, which will arise, are acknowledged and managed in a transparent way. Full details of the types and level of interest and how they should be declared will be in the clinical senate's conflict of interest policy.

In addition, an individual may have a conflict of loyalties i.e. where decision-makers have competing loyalties between the organisation to which they have primary duty and some other person or entity. For healthcare professionals, this could include loyalties to a particular professional body, society or special interest group. This could also involve an interest in a particular condition or treatment due to an individual's own experience or that of a family member.

This can include situations where clinical review team members are likely to have long-standing professional relationships with colleagues affected by commissioning advice, to whom they may have allegiances as peers, and with whom they developed particular ways of working over a period of time. Personal conflicts could

therefore exist when advice is made which could affect such relationships in some way.

Members of the clinical review team are intended to act independently, i.e. they do not represent their employing organisation or professional body. If, at any time, they consider that a conflict of loyalty may exist, then the individual concerned should assume that a potential conflict of interest exists, it should be declared and their membership of the review team reviewed.

A direct interest would normally mean that it would be difficult for the individual to participate fully in the review without any conflict or impartiality and it may be inappropriate for them to be included in the review team.

Where an individual declares an indirect interest this may not automatically exclude them from the team. It is recommended that in such cases, the clinical senate council chair, the chair / lead member of the review team and the lead member of the sponsoring organisation consider the degree of interest and discuss, on a case by cases basis, whether it is appropriate for the individual to be a member of the team or not . It may be beneficial to include the individual in the discussion; the senate manager is also able to offer advice.

7) Clinical review methodology

The actual methodology of the review will be determined by the size, nature and complexity of the service change proposal. The fundamental principle and purpose of the clinical review is to provide independent clinical advice to NHS England that the proposed case for service change meets the test that there is ‘a clear clinical evidence base’.

A starting point that goes to the heart of the public’s and patient’s interests is what will the impact on quality (safety, clinical effectiveness and patient experience) be if this scheme goes ahead, how will quality be changed, in what way and by how much?

In undertaking this work a clinical review team may wish to consider whether:

i. there is robust evidence underpinning both the clinical case for change and the proposed clinical model;
ii. the relevant available evidence been effectively marshalled and applied to the specifics of the proposed scheme
iii. there is alignment with other national, regional and local intentions; and
iv. there is evidence of clinical overstatement or optimism bias in the proposals.

The clinical review team will review the case for change and options appraisal.
The clinical review team should consider (but is not limited to) the following questions:

i. Will these proposals deliver real benefits to patients?
ii. Is there evidence that the proposals will improve the quality, safety and sustainability of care?
iii. Do the proposals reflect up to date clinical guidelines and national and international best practice e.g. Royal College reports?
iv. Do the proposals reflect the goals of the NHS Outcomes Framework?
v. Do the proposals reflect the rights and pledges in the NHS Constitution?
vi. Do the proposals align with local joint strategic needs assessments, commissioning plans and joint health and wellbeing strategies?
vii. Do the proposals meet the current and future healthcare needs of their patients?
viii. Is there a clinical risk analysis of the proposals, and is there a plan to mitigate identified risks?
ix. Do the proposals demonstrate good alignment with the development of other health and care services?
x. Do the proposals support better integration of services?
xi. Do the proposals consider issues of patient access and transport? Is a potential increase in travel times for patients outweighed by the clinical benefits?
xii. Will the proposals help to reduce health inequalities?
xiii. Does the options appraisal consider a networked approach - cooperation and collaboration with other sites and/or organisations?

Clinical review teams are not expected to advise or make comment upon on issues of the NHS England assurance process that will be reviewed elsewhere (e.g. patient engagement, GP support or the approach to consultation).

A suggested methodology would include:

i. Examination of key background documents and information provided by the sponsoring organisation . As a minimum this would include the case for change, proposed clinical models and relevant activity information. The information required will be specified in the Terms of Reference.
ii. Development of questions from the examination of information to inform -
iii. Interviews with key stakeholders associated with the proposals. These will be identified on a case by case basis but typically might include the programme senior responsible owner, programme lead clinician, local GPs, medical directors, programme clinical leads, community services staff.
iv. Seeking the views of staff in the key clinical areas affected by the proposed changes. For complex cross-sector, multi-speciality change proposals this might require a panel approach, focus groups or other arrangements that allow the review team to meet with large numbers of key clinical and managerial figures.
v. Where appropriate, visiting the key sites or services in question, allowing for on-site clinician to clinician discussion. For whole system proposals it will be important to consider clinical views from the primary, secondary, tertiary and community sectors.

The review of documents, information gathered from interviews and discussions with key figures, any site visits and subsequent enquiries will all inform the clinical review team report. A draft report will be provided to the sponsoring organisation for fact checking purposes only. A suggested report structure is attached at Appendix iv.

Decision Making

The Independent Clinical Review Panel should assess the strength of the evidence base of the case for change and proposed models. Where the evidence base is weak then clinical consensus, using a voting system if required, will be used to reach agreement. The voting will be recorded, and dissenting views will be noted. The Clinical Senate Review should indicate whether recommendations are based on high quality clinical evidence e.g. meta-analysis of randomised controlled clinical trials or clinical consensus e.g. Royal College guidance, expert opinion.

8) Consideration of the review findings

The clinical review team will draft a review report and, prior to submission to clinical senate council for its consideration, the team will provide a copy to the sponsoring organisation for factual accuracy checking purposes only (this will be built into the timeline).

Once the sponsoring organisation has responded and any factual inaccuracies amended, the draft report will be submitted to clinical senate council. Clinical senate council will be asked to consider the review team's findings and comment specifically on the:

i. comprehensiveness and applicability of the review
ii. content and clarity of the review and its suitability to the population in question
iii. interpretation of the evidence available to support its recommendations
iv. likely impact on patient groups affected by the guidance
v. likely impact / ability of the health service to implement the recommendations.

In considering the review team report, senate council should ensure that the terms of reference have been fulfilled and that the advice is sense checked, clear and evidence based. The council may also wish to take a view on any specific issues highlighted by the clinical review team, or offer advice on issues that should be taken into consideration in implementing change including unintended consequences and sustainability.

Comments received from the clinical review team will be considered by the clinical senate council. Once the draft is finalised, members of the clinical review team will be asked to formally approve the advice and report for submission to the sponsoring organisation. The review report is then endorsed by clinical senate council who take formal responsibility for the report and issue it to the sponsoring organisation.

9) Clinical review report

Clinical Senate review reports should use clear, unambiguous language, clearly defining terms used to ensure shared understanding by all users.

The review report will contain information specifically for sponsoring organisations. It is not intended to provide detailed clinical recommendations or a description of how the change may be implemented.

The review report is issued to the sponsoring organisation and then forms part of the formal evidence of NHS England's assurance process. The review report remains confidential for the duration of that process; the assumption should be that clinical senate review reports will be placed in the public domain at the conclusion of the NHS England assurance process.

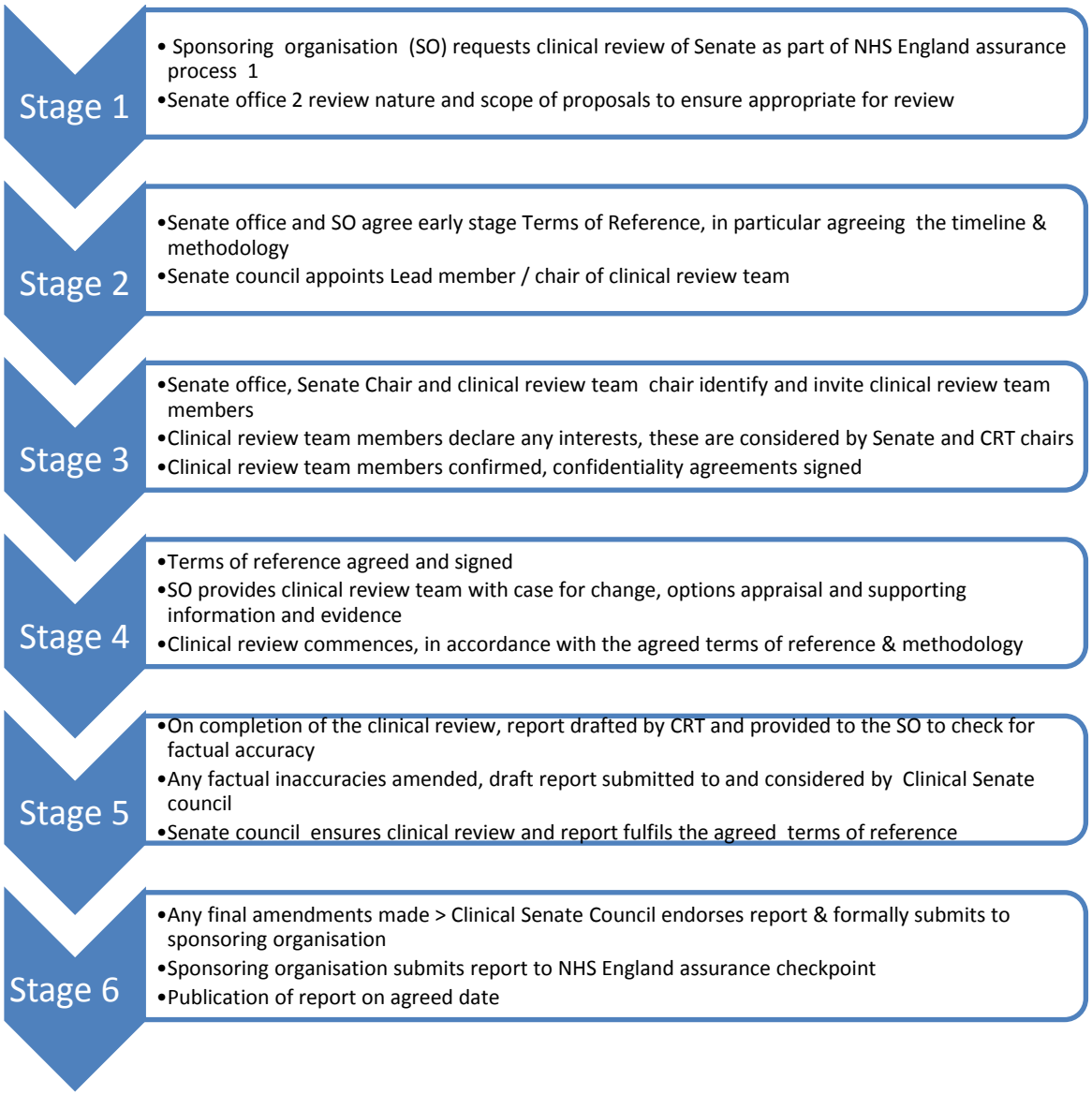
The review report template at Appendix iv is intended to aid consistency between clinical review teams, it is suggested that the format below is used by Clinical Senates when drawing up the reports of their clinical reviews, adding additional information and tailoring where local adaptation is required.

10) Managing communications

- For NHS England assurance process the responsibility for communication and media handling lies with NHS England.
- The communication plan will be agreed when the terms of reference of the review are agreed
- The Clinical Senate's role within that should be agreed at an early stage in the process and reflected in the Terms of Reference.

- The report must be published at a time at the discretion of the sponsoring organisation and in line with the agreed communication plan .It would be good practice to publish as soon as possible.

Figure B: Clinical review process



1. *This assumes applies to Stage 2 of the NHS England assurance checkpoint – see figure A page 4 and assumes that all information, case for change etc is ready*

2. *'Senate office' will include at least the Senate Chair, and two other members of Council and Senate Manager to be determined by each Senate*

Appendix i

CLINICAL REVIEW: TERMS OF REFERENCE

Title:

Sponsoring Organisation:

Clinical Senate:

NHS England regional or area team:

Terms of reference agreed by:

(Name)

on behalf (name) Clinical Senate and

(Name)

on behalf of sponsoring organisation (name)

Date:

Clinical review team members

Chair or lead member (appointed by clinical senate council chair)

The clinical review team is likely to include members from within its own clinical senate but may also include members of other clinical senates, or other invited relevant topic experts. For example, clinical specialists (who may, or may not, come from outside the senate geographical area) and strategic clinical network members.

Members of the clinical review team should be drawn from the following, this is not an exclusive list but provided as a guide as membership will need to be appropriate to the topic under review:

a. Patient / citizen representatives
b. Commissioners: CCGs, NHS England Area Team

c. Providers: primary, secondary, community, mental health, social care, other e.g. Ambulance trust
d. Clinical experts
e. Public Health

Aims and objectives of the clinical review

The clinical review team needs to have a clear focus on what it is being asked to do. Its focus should be on the areas agreed with the sponsoring organisation - the foundation of which is to test if there is 'a clear clinical evidence base' underpinning the proposals.

Scope of the review

[*Clinical areas under consideration to be clearly defined*]

Timeline

[*Agreed timeline to be inserted, to include stages of early discussion, establishment of clinical review team, information gathering, team brief, review, consideration, report writing, reporting to council, commissioner feedback and response date to sponsoring organisation]*

Reporting arrangements

The clinical review team will report to the clinical senate council which will agree the report and be accountable for the advice contained in the final report.

Clinical senate council will submit the report to the sponsoring organisation and this clinical advice will be considered as part of the NHS England assurance process for service change proposals.

Methodology

[*Define how the review will be undertaken, including information required in advance, approach to interviews, any site visits. This should be agreed with the sponsoring organisations proposing the service change as they will need to support the review requests*.]

Report

A draft clinical senate assurance report will be made to the sponsoring organisation for fact checking prior to publication

Comments/ correction must be received within [x] working days.

The final report will be submitted to the sponsoring organisation by [date]

Communication and media handling

Dates and arrangements for publication and dissemination of report and associated information. To include identified lead person, where and when report will be published, press releases/conferences, meetings with patent groups, public, staff and boards, health and wellbeing boards and Health overview and scrutiny committees

Resources

The [regional] clinical senate will provide administrative support to the review team , including setting up the meetings and other duties as appropriate.

The clinical review team will request any additional resources, including the commissioning of any further work, from the sponsoring organisation.

Accountability and Governance

The clinical review team is part of the [regional] Clinical Senate accountability and governance structure.

The [regional] clinical senate is a non statutory advisory body and will submit the report to the sponsoring organisation.

The sponsoring organisation remains accountable for decision making but the review report may wish to draw attention to any risks that the sponsoring organisation may wish to fully consider and address before progressing their proposals.

Functions, responsibilities and roles

The **sponsoring organisation** will

i. provide the clinical review panel with the case for change, options appraisal and relevant background and current information, identifying relevant best practice and guidance. Background information may include, among other things, relevant data and activity, internal and external reviews and audits, impact assessments, relevant workforce information and population projection, evidence of alignment with national, regional and local strategies and guidance (e.g. NHS Constitution and outcomes framework, Joint Strategic Needs Assessments, CCG two and five year plans and commissioning intentions). The sponsoring organisation will provide any other additional background information requested by the clinical review team.
ii. respond within the agreed timescale to the draft report on matter of factual inaccuracy.
iii. undertake not to attempt to unduly influence any members of the clinical review team during the review.
iv. submit the final report to NHS England for inclusion in its formal service change assurance process.

Clinical senate council and the sponsoring organisation will

i. agree the terms of reference for the clinical review, including scope, timelines, methodology and reporting arrangements.

Clinical Senate council will

i. appoint a clinical review team, this may be formed by members of the senate, external experts, and / or others with relevant expertise. It will appoint a chair or lead member.
ii. endorse the terms of reference, timetable and methodology for the review
iii. consider the review recommendations and report (and may wish to make further recommendations)
iv. provide suitable support to the team and
v. submit the final report to the sponsoring organisation

Clinical review team will

i. undertake its review in line the methodology agreed in the terms of reference
ii. follow the report template and provide the sponsoring organisation with a draft report to check for factual inaccuracies.
iii. submit the draft report to clinical senate council for comments and will consider any such comments and incorporate relevant amendments to the report. The team will subsequently submit final draft of the report to the Clinical Senate Council.
iv. keep accurate notes of meetings.

Clinical review team members will undertake to

i. commit fully to the review and attend all briefings, meetings, interviews, panels etc that are part of the review (as defined in methodology).
ii. contribute fully to the process and review report
iii. ensure that the report accurately represents the consensus of opinion of the clinical review team
iv. comply with a confidentiality agreement and not discuss the scope of the review nor the content of the draft or final report with anyone not immediately involved in it. Additionally they will declare, to the chair or lead member of the clinical review team and the clinical senate manager, any conflict of interest prior to the start of the review and /or materialise during the review.

END

Appendix ii

Declaration of Conflict of Interest: template

The following template is suggested as a guide for all members of a clinical review team to complete. Clinical Senate Council members should also consider if they have any conflicts in considering the review team's report.

For advice on what items should and should not be declared on this form refer to the Conflicts of Interest Policy issued by the respective clinical senate. Further advice can also be obtained from the Clinical Senate Manager.

Name:

Position:

Please describe below any relationships, transactions, positions you hold or circumstances that you believe could contribute to a conflict of interest:

Type of Interest – Please supply details of where there is conflict in accordance with the following list

a) A direct pecuniary interest: where an individual may financially benefit from the consequences of a commissioning decision (for example, as a provider of services);

b) An indirect pecuniary interest: for example, where an individual is a partner, member or shareholder in an organisation that will benefit financially from the consequences of a commissioning decision;

c) A direct non-pecuniary interest: where an individual holds a non-remunerative or not-for profit interest in an organisation, that will benefit from the consequences of a commissioning decision (for example, where an individual is a trustee of a voluntary provider that is bidding for a contract);

d) An indirect non-pecuniary interest: where an individual is closely related to, or in a relationship, including friendship, with an individual in categories a-f.

e) A direct non-pecuniary benefit: where an individual may enjoy a qualitative benefit from the consequence of a commissioning decision which cannot be given a monetary value (for example, a reconfiguration of hospital services which might result in the closure of a busy clinic next door to an individual's house);

f) An indirect non-pecuniary benefit: where an individual may enjoy a qualitative benefit from the consequence of a commissioning decision which cannot be given a monetary value but is a benefit to peers or colleagues (for example, a recommendation which results in an increase in revenue or status to their employing organisation or results in their organisation becoming the preferred provider).

g) An indirect non-pecuniary conflict: where the evidence of the senate may bring a member into direct or indirect conflict with their contracting or employing organisation, to the extent that it may impair the member's ability to contribute in a free, fair and impartial manner to the deliberations of the senate council, in accordance with the needs of patients and populations.

h) Other – please specify

Name	
Type of interest declared (if none state NONE here)	
Details of interest	
Detail of how interest considered (e.g. discussion, email, meeting)	
Action taken (i.e. remain in review team or withdraw)	
Action taken by & date	
Date of declaration	

I hereby certify that the information set forth above is true and complete to the best of my knowledge.

Signature:

Name:

Date:

END

Appendix iii

Confidentiality agreement template

XXX Clinical Senate clinical review team confidentiality agreement

I (*name*) ……. hereby agree that during the course of my work (as detailed below) with the XXXX clinical senate I am likely to obtain knowledge of confidential information with regard to the business and financial affairs of an NHS body, or other provider, its staff, clients, customers and suppliers, details of which are not in the public domain ('confidential information') and accordingly I hereby undertake to and covenant that:

- I shall not use the confidential information other than in connection with my work; and
- I shall not at any time (save as required by law) disclose or divulge to any person other than to officers or employees of XXXX clinical senate, other NHS organisations, staff, clients, customers and suppliers whose province it is to know the same any confidential information and I shall use my best endeavours to prevent the publication or disclosure of any confidential information by any other person.

The restrictions set out above shall cease to apply to information or knowledge that comes into the public domain otherwise than by reason of my default of this Agreement.

The 'Work' (clinical review) is: _____

_____

_____

Signed _____ Date: _____

Name (caps) _____ END

Appendix iv

Clinical senate clinical review team report regarding the [name] proposed service change

Clinical Senate

[senate email]@nhs.net

Date of publication to sponsoring organisation:

Panel chair foreword

Clinical Senate Chair summary and key recommendations

BACKGROUND

[CLINICAL AREA]

[Description of current service model]

[Case for change]

[Review methodology]

Details of approach taken, review team members, documents used, sites visited, interviewees

[Scope and limitations of review]

[Recommendations] CONCLUSIONS AND ADVICE

[References]

This should include advice against the test of 'a clear clinical evidence base' for the proposals and the other checks defined in the terms of reference agreed at the outset of the review.

Has the proposal been founded on robust clinical evidence? What evidence has been used and how has it been applied to local circumstances?

Has the available evidence been marshalled effectively and applied to the specifics of the proposed scheme?

GLOSSARY OF TERMS

APPENDICES:

1. Terms of reference
2. Clinical review team members and any declarations of interest
3. Background information (*NB this should be a summary and is not intended to be the set of evidence or information provided*)

END