NHS
West Midlands Clinical Senate

STAGE 2 CLINICAL ASSURANCE EVIDENCE FRAMEWORK

This document sets out advice to proposers in relation to the evidence to be developed in advance of an independent clinical review as part of NHSE Stage 2 assurance processes.

Version 1.1 – June 2017

West Midlands Clinical Senate

Introduction by the Chair of the West Midlands Clinical Senate

Service change assurance exists to give confidence to the NHS and public that proposals are well thought through, have taken on board a wide range of views and will deliver real benefits. At the heart of the NHS England assurance process are the 'five tests for service change' that are in the government's mandate to NHS England, as updated in *Next Steps on the Five Year Forward View* (NHSE, 2017). One of these five mandatory tests is that a clear clinical evidence base underpins service change proposals.

Stage 2 is a formal assurance checkpoint, which builds on the strategic sense check. It involves assurance of the proposals against the five tests and best practice checks examining all aspects of the plans. These include clinical quality and strategic fit, finance, workforce, activity, programme management arrangements, travel impact, resilience, communications and engagement and use of information technology. Stage 2 must take place in advance of any wider public involvement, formal consultation process or a decision to proceed with a particular option.

A clinical senate can only undertake a review and provide advice following a formal request from the 'sponsoring organisation' – either the commissioner leading the service change proposal or the relevant NHS England regional team. The decision to request an NHS England Stage 2 external clinical assurance review should follow discussions between the relevant commissioner(s) and NHS England at the strategic sense check stage of the process, and may be informed by clinical senate advice on the development and clinical assurance of proposals.

There is a growing body of anecdotal evidence from senates, both locally and nationally, which suggests that sponsoring organisations may approach clinical senates for NHS England Stage 2 clinical reviews without sufficient preparation, and do not always have detailed evidence available regarding proposed service changes. Clinical senates need to be assured from the outset (pre-review stage) that the detail to support proposals is robust and evidence based. There is a resource implication in convening an independent clinical review panel of experts, especially as members are usually clinicians, and committing to the process takes time away from direct patient care. It is important to use that resource as effectively as possible.

Working with Clinical Senates nationally, the West Midlands Clinical Senate commissioned the Strategy Unit to develop this evidence framework in order to help sponsoring organisations ensure that they are building the required evidence from the outset, minimising the risk of any delay.

Professor Adrian Williams – Chair, West Midlands Clinical Senate

Notes

1. The purpose of this advice is to assist the proposers of major service change in developing the clinical evidence to support their proposals. That evidence is required to inform an independent clinical review of the proposals as part of NHS England's Stage 2 Assurance process. Proposing bodies should consult NHS England guidance[1] and seek advice from the relevant NHS England Regional Office in determining the specific assurance requirements for their proposals. This advice assumes that it has been determined that Stage 2 clinical assurance is required.

2. An assessment of the readiness of proposals for a Stage 2 review will be made by the Senate, based on the evidence required, prior to identifying a review panel and scheduling panel meetings. This is so that clinical panel members are not asked to cancel clinical sessions until there is clarity on a scheme's readiness to undergo a Stage 2 review. This framework sets out the evidence that the Senate's Independent Clinical Review Panels may require proposers to provide in advance of a Stage 2 clinical review, and gives clarity to proposers in relation to the evidence likely to be required.

3. National Senate guidance[2] states that *the clinical review team will review the case for change and options appraisal.* It sets out thirteen questions which are to be considered and highlights that proposals should be reviewed *against the appropriate key test (clinical evidence base) and the best practice checks that relate to clinical quality*. This framework reflects those questions and has also been informed by an evidence scan from sources including NCAT and Senate review, NHSE and Royal College guidance, reconfiguration proposals and reports by the King's Fund and the Independent Reconfiguration Panel. In addition, its development has been shaped by a stakeholder group comprising both proposers and reviewers, and has drawn on experience from a number of regions.

4. Two versions of the framework are provided. Whilst they both contain the same advice, they are structured for differing purposes:

    a. The first directly follows the thirteen questions, providing an explicit audit trail back to the guidance under which reviews are conducted.

    b. The second re-presents the framework in a way that supports the population of common sections of the Pre Consultation Business Cases that lead commissioners are required to develop at Stage 2.

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[1] *Planning, assuring and delivering Service Change for Patients*, NHS England (2015)
[2] *Clinical Senate Review Process – Guidance Notes*, NHS England (2014)

5. Notwithstanding the advice in this framework, scheme proposers are encouraged to use their own judgement in terms of the evidence appropriate to their specific proposals. Variations to the framework for a specific scheme (standing items that are not relevant and/or additional items specific to particular schemes) may be highlighted by the Senate either as part of its report and recommendations following Stage 1 review or through the process to agree the Terms of Reference for the Stage 2 review.

6. The Senate recognises the constraints under which proposers may be working and advises schemes to factor the requirements of the framework into the development of their proposals and the associated programme timelines from an early stage. The framework is a tool for shaping the evidence from the outset as well as assessing the final readiness of proposals for review. As proposals (and their associated evidence) are developed, proposers are advised to keep the Senate and NHS England informed of their progress. This should minimise the risk of any delay.

7. The review process itself will take approximately three months from the point at which a scheme's readiness is confirmed by the Senate. This is subject to external constraints such as those around pre-election periods when publication of decisions around potentially contentious proposals should be avoided. Proposers will need to take such factors into account in planning their time lines.

8. Where there are multiple services to be considered, a single submission should be made rather than separate evidence packs for each service.

Senate Questions Structure

	Question		Evidence Required	Further detail on evidence required
1	Will these proposals deliver real benefits to patients?	It is intended that responses to this section should provide a high level summary of the current position, future proposals and supporting evidence. As such it serves as an executive summary to give panel members an overview, with detailed evidence being supplied in appendices or in response to subsequent questions.		
		a	Provide a narrative summary of the current position in respect to the services covered by your proposals.	This should provide an overview of the current service provision including relevant geographic, demographic and service configuration information plus details of any recent clinical service or other organisational changes. [It is recognised that services are continually changing and that what is provided will only reflect a point in time.]
		b	Set out the case for why proposals for change need to be considered	i) Ensure that each main clinical driver is supported with robust evidence, quantified where possible: e.g. relevant CQC reports, evidence of clinical variation, clinical workforce data, patient experience information, clinical audits, extent of compliance with guidance. ii) The opportunity cost of not undertaking major service change might also be set out. iii) Non-clinical drivers should be referenced but not evidenced.
		c	Summarise your proposals for change	Set out: i) Which services are in scope or are interdependencies/out of scope. ii) Proposed changes to service delivery, activity, estates configuration, workforce model, etc. Relevant patient pathways should be illustrated (both current and future state). Consideration of impact should be across the whole pathway - self-care, primary care, acute, community and to end of life.

	Question		Evidence Required	Further detail on evidence required
		d	Describe and quantify the benefits which you expect your proposals to deliver.	i) A summary of key benefits should be provided and a detailed Benefits Realisation Plan (which quantifies with timescales the extent of the improvements expected) should be attached as an appendix. ii) Include information on how the proposed changes will be evaluated, measures of success and metrics that will be used
		e	Evidence the extent to which local clinicians and communities believe the proposals will deliver real benefits for service users and carers in the affected populations.	iii) Summary of public/clinical involvement and engagement including materials used and events held. iv) Evidence of how the proposal takes into account the emerging findings of the Equalities Analysis and other impact assessments. v) Details of key current or expected challenges to proposals (including an evidenced assessment of the strength/breadth of support for challenges) and of your responses to those challenges. vi) Detail the names/roles of local clinical and patient champions for proposals. vii) Provide written evidence from local clinical/patient bodies confirming explicit support for the proposals and highlighting any remaining areas of concern to them (e.g. CCG AOs, LMC, GP Federation, relevant medical and nursing directors, Healthwatch, groups representing affected service users/carers, Health and Wellbeing Board Chair). CCG letters should confirm the affordability of proposals (no detailed financial information will be required by the Senate).

	Question		Evidence Required	Further detail on evidence required
2	Is there evidence that the proposals will improve the quality, safety and sustainability of care?	a	Describe and evidence the impact that proposals are expected to have on the safety, effectiveness and experience of care (including in scope and out of scope/interdependent services)	i) Provide clinical and other evidence which you believe supports your proposals: e g. peer review, independent panel assessment, outcomes data from comparable schemes. ii) Include a summary of all the evidence provided and set out the nature of that evidence (e.g. meta-analysis, systematic review, randomised controlled trials, other studies, expert clinical opinion/patient experience, Quality Impact Assessment). iii) Where there is no directly relevant evidence base, provide evidence from appropriate parallels/proxies to support your proposals. iv) Where new technology is key to the delivery of proposals, provide evidence of its existence, functionality and effectiveness.

	Question		Evidence Required	Further detail on evidence required
		b	Describe and evidence the impact that proposals are expected to have on the sustainability of affected and related services (including those in other health economies)	i) Proposals should demonstrate compliance with national guidance on workforce requirements. Where proposals do not comply or involve models of care not covered by guidance, an independent assessment should be undertaken and provided. Evidence of engagement with Health Education England and the outcome of that engagement should also be provided. ii) Proposals should set out their sustainability in terms of clinical workforce by supplying (where available) relevant: • a workforce plan broken down by discipline, grade and site (and covering current staff levels and the alignment of future staff levels with activity projections (see Q7) and/or national guidelines) • clinical rotas (PAs not WTE) for all services affected including interdependent services across sites and in affected providers across primary, acute and community care • analysis of competencies/skill mix required • recruitment and retention plans (including associated training requirements) • research and innovation plans • IT Clinical System Plans • outline plans for how any working practices/cultures will be changed, where this is required for successful implementation • Staff engagement and plans to support staff transition.
		c	Describe how the performance of current services will be sustained throughout the lifecycle of the reconfiguration programme	• Business continuity plans, network support arrangements, assessment of the potential need for emergency measures (with details of any associated governance processes). • Provide evidence of Communication and Engagement Plans

	Question		Evidence Required	Further detail on evidence required
		d	Describe your outline plans for how proposals would be implemented.	This should cover i) Provision for clinical leadership for implementation ii) Plans for maintaining clinical involvement and support iii) Supporting transformation capacity and capability.
		e	Set out the expected impact of estates changes on the safety, effectiveness and experience of care.	Evidence of compliance/clarity of derogation from Health Building Notes, compliance with privacy and dignity requirements, BREEAM assessment, etc.
3	Do the proposals reflect up to date clinical guidelines and national and international best practice, e.g. Royal College reports?		Summarise the requirements of guidance/best practice documents relating to affected services and how your proposals align with these.	This could be done in tabular form and/or through a review against relevant WMQRS Quality Standards (detail should be covered in Q2). This should include any guidance about the appropriate scale of catchment populations/activity volumes and how proposals comply with these.
4	Do the proposals reflect the goals of the NHS Outcomes Framework?		Provide a summary of how your proposals would support each relevant domain of the outcomes framework.	This could be done in tabular form, linking to other sections as required. Where there is any potential adverse impact this should be made explicit and a summary of the proposed mitigation provided. i) Domain 1 - Preventing people from dying prematurely ii) Domain 2 - Enhancing quality of life for people with long-term conditions iii) Domain 3 - Helping people to recover from episodes of ill health or following injury iv) Domain 4 - Ensuring that people have a positive experience of care v) Domain 5 - Treating and caring for people in a safe environment and protecting them from avoidable harm

	Question		Evidence Required	Further detail on evidence required
5	Do the proposals reflect the rights and pledges in the NHS Constitution?		Provide a narrative summary of how your proposals would support the rights and pledges in the NHS Constitution.	This could be done in tabular form, linking to other sections as required. Where there is any potential adverse impact this should be made explicit and a summary of the proposed mitigation provided. i) rights about access to health services ii) rights about quality of care and environment, such as the provision of same-sex hospital accommodation iii) rights about treatments and drugs- rights about consent and confidentiality iv) rights about patient choice v) rights about your own involvement in your healthcare – for example, through schemes such as personal health budgets vi) rights to complaints and redress
6	Do the proposals align with local joint strategic needs assessments, commissioning plans and joint health and wellbeing strategies?		Provide a summary of relevant local strategic needs analyses and commissioning plans and of how your proposals address those needs and complement those plans.	This could be done in tabular form, linking to other sections as required, and should include. i) Consideration of commissioning plans should include all relevant commissioners – NHSE, CCGs, local authorities (social care and public health). ii) Engagement with/support from Health and Wellbeing Boards should be covered under Q1e.

	Question		Evidence Required	Further detail on evidence required
7	Do the proposals meet the current and future healthcare needs of their patients?		Set out the projected activity and capacity levels for the affected services, reflecting the proposed patient pathway(s).	i) The modelling of the future state should consider the implications of anticipated changes; • in demography, population health status and patient expectations • in healthcare policy and service standards • in medical technologies • associated with other concomitant reconfigurations. ii) Describe the process through which activity models were developed and detail the assumptions used. The models should describe the level, nature and distribution of activity; • in a baseline year (actual) • that would have been required to meet demand in the baseline year (actual and unmet demand) • that would be required without reconfiguration to meet demand at some point in the future (future : do nothing) • that would be required with reconfiguration to meet demand at some point in the future (future : proposed) The time horizon for the modelled future states should be selected with reference to the timescales for the proposed reconfiguration. iii) Models should convert activity into the required capacity setting out the number and type of staff required and the level and type of infrastructure (e.g. beds, theatres). iv) Analysis should identify those assumptions on which the modelled futures states are particularly sensitive. v) The models should clearly articulate any material implications for aligned services and sectors (e.g. repatriation of patients from specialist centres for subsequent phases of care). Evidence of agreement in principle from those other services should be provided.

	Question		Evidence Required	Further detail on evidence required
8	Is there a clinical risk analysis of the proposals, and is there a plan to mitigate identified risks?		Set out your appraisal of the risks of implementing the proposals.	For each risk identified, summarise key mitigating actions proposed. This should include: i) The safety, effectiveness or experience of patient care ii) The deliverability of your proposals - potential adverse impacts on related/co-dependent services (including destabilisation of services) iii) Proposed physical solutions iv) The accuracy of activity, capacity, workforce projections and workforce risks v) Formal modelling of any impact on Emergency Preparedness, Resilience and Response (EPRR) plans with mitigation where required.
9	Do the proposals demonstrate good alignment with the development of other health and care services?		Describe the alignment between your proposals and wider system plans (e.g. local Sustainability and Transformation Plans).	i) Evidence of engagement with other relevant providers/health economies should be included (e.g. neighbouring Trusts, ambulance services) along with the outcome of that engagement especially in relation to issues of clinical and financial sustainability. ii) If local public health/social care plans and plans of specialised commissioners are not contained in system plans they must be separately referenced. iii) Where proposals involve significant hospital bed closures, proposers must also demonstrate that they can meet one of three conditions: • That sufficient alternative provision, such as increased GP or community services, is being put in place alongside or ahead of bed closures, and that the new workforce will be there to deliver it; and/or • That specific new treatments or therapies, such as new anti-coagulation drugs used to treat strokes, will reduce specific categories of admissions; and/or • Where a hospital has been using beds less efficiently than the national average, that it has a credible plan to improve performance without affecting patient care (for example in line with the Getting it Right First Time programme).

	Question		Evidence Required	Further detail on evidence required
10	Do the proposals support better integration of services?		Describe how your proposals support integrated working.	i) This includes integration with other health and social care services. ii) For hospital proposals, drawings showing changes in physical adjacencies should be provided. iii) Evidence of planning related to the integration of services should set out how independent living, self-management and self-care will be promoted and supported.
11	Do the proposals consider issues of patient access and transport? Is a potential increase in travel times for patients outweighed by the clinical benefits?		Provide modelling of the impact of your proposals on patient access, reflecting the proposed patient pathway(s).	i) Analysis should show the patient travel times and distances using road networks and drive times and, where appropriate, public transport routes and timetables. In additional to total and average (median) travel times and distances, analysis should also show the changes in the distribution of times and distances and identify geographic areas where residents travel times might be substantially altered as a result of the proposed reconfiguration. ii) The default assumption in any service modelling should be that patients will normally travel to their nearest suitable provider. Where different assumptions are used proposers should be set out the rationale behind these assumptions, and the results compared to those under the default assumption. iii) Travel time analysis should where appropriate consider the implications of any service reconfiguration on families and carers, and mitigating actions should be included. iv) Evidence of impact on ambulance services and/or other affected patient transport service should be set out with confirmation of support from affected providers.
12	Will the proposals help to reduce health inequalities?		Summarise the expected impact of your proposals on health inequalities including areas of direct benefit and mitigations where there is a risk of increasing disadvantage for some groups.	i) As a minimum a robust Equalities Analysis should be included. Ideally this should be submitted as part of an Integrated Impact Assessment appropriate to the pre-consultation Options stage (in line with guidance in the *Integrated Impact Assessment Toolkit*). ii) Proposals should describe the issues/concerns raised by groups with protected characteristics and how they have been/will be adapted in response.

	Question		Evidence Required	Further detail on evidence required
13	Does the options appraisal consider a networked approach - cooperation and collaboration with other sites and/or organisations?		Set out the range of options you have considered, including alternatives to reconfiguration.	Evidence could include: i) Detailed reports on option development and appraisal processes and outcomes (including the 'do nothing' and excluded options with rationale for exclusion/preference) ii) Describe alternative solutions/staffing models considered with rationale for exclusion (e.g. Would it be possible to achieve the same benefits through redesigned and shared rotas? Where reconfiguration involves skill-mix changes, for example shift of activities to nurse practitioners in Minor Injury Units instead of ED, has the impact on doctors' job plans been worked through?)
14	Have you addressed the issues/recommendations raised by Senate in your Stage 1 Review?		Provide a summary narrative addressing Stage 1 issues/recommendations.	These could be referenced to where supporting evidence can be found in responses to other parts of the framework.

Alternative PCBC Structure

	Evidence required	Further guidance on evidence required
Indicative PCBC Sections and guidance		
1. Executive Summary		
Briefly summarise the purpose and main contents of the PCBC.		
2. Introduction/Background		
a)	Provide a narrative summary of the current position in respect to the services covered by your proposals.	This should provide an overview of the current service provision including relevant geographic, demographic and service configuration information plus details of any recent clinical service or other organisational changes. [It is recognised that services are continually changing and that what is provided will only reflect a point in time.]
3. Case for Change		
Outline the case for change. • *Commissioners should oversee the development of the clinical case for change, as part of the outline case. Medical directors and heads of clinical services of any providers involved can help build the clinical evidence base.* • *Commissioners should assure themselves that they have sought a comprehensive range of perspectives for the case for change. Proposals should be discussed with NHS Improvement where appropriate. This will be particularly important where trusts will need to access Public Dividend Capital to deliver options which may be consulted upon.*		
a)	Set out the case for why proposals for change need to be considered	i) Ensure that each main clinical driver is supported with robust evidence, quantified where possible: e.g. relevant CQC reports, evidence of clinical variation, clinical workforce data, patient experience information, clinical audits, extent of compliance with guidance. ii) The opportunity cost of not undertaking major service change might also be set out. iii) Non-clinical drivers should be referenced but not evidenced.
4. Vision/Key Benefits		
Be clear about the impact in terms of outcomes.		
a)	Describe and quantify the benefits which you expect your proposals to deliver.	A summary of key benefits should be provided and a detailed Benefits Realisation Plan (which quantifies with timescales the extent of the improvements expected) should be attached as an appendix.

	Evidence required	Further guidance on evidence required
5. Proposed Model of Care		
This section should include: • *Analysis of demographic and other factors likely to influence future demand for the service. Be explicit about the number of people affected and the benefits to them.* • *Links to relevant JSNAs and JHWSs, and CCG and NHS England commissioning plans.* • *Identification of any clinical co-dependency issues, including any potential impact on the current or future commissioning or provision of specialised or other services.* • *Service reconfiguration must be evidence-based and this evidence should be publicly available during the consultation and decision making stages. This ensures service reconfiguration proposals are underpinned by clear clinical evidence and align with clinical guidance and best practice.* • *Examples of service models and learning from elsewhere including national / international experience.* • *Demonstration of how the proposals meet the five tests. [This is likely to be a thread throughout the document but a summary assessment should be included here.]*		
a)	Summarise your proposals for change	Set out: i) Which services are in scope or are interdependencies/out of scope. ii) The proposed changes to service delivery, activity, estates configuration, workforce model, etc. Relevant patient pathways should be illustrated (both current and future state). Consideration of impact should be across the whole pathway - self-care, primary care, acute, community and to end of life.
b)	Describe and evidence the impact that proposals are expected to have on the safety, effectiveness and experience of care (including in scope and out of scope/interdependent services)	i) Provide clinical and other evidence which you believe supports your proposals. e.g. peer review, independent panel assessment, outcomes data from comparable schemes. ii) Include a summary of all the evidence provided and set out the nature of that evidence (e.g. meta-analysis, systematic review, randomised controlled trials, other studies, expert clinical opinion/patient experience, Quality Impact Assessment). iii) Where there is no directly relevant evidence base, provide evidence from appropriate parallels/proxies to support your proposals. iv) Where new technology is key to the delivery of proposals, provide evidence of its existence, functionality and effectiveness.
c)	Summarise the requirements of guidance/best practice documents relating to affected services and how your proposals align with these.	This could be done in tabular form and/or through a review against relevant WMQRS Quality Standards. This should include any guidance about the appropriate scale of catchment populations/activity volumes and how proposals comply with these.

	Evidence required	Further guidance on evidence required
d)	Set out the projected activity and capacity levels for the affected services, reflecting the proposed patient pathway(s).	i) The modelling of the future state should consider the implications of anticipated changes • in demography, population health status and patient expectations • in healthcare policy and service standards • in medical technologies • associated with other concomitant reconfigurations. ii) Describe the process through which activity models were developed and detail the assumptions used. The models should describe the level, nature and distribution of activity • in a baseline year (actual) • that would have been required to meet demand in the baseline year (actual and unmet demand) • that would be required without reconfiguration to meet demand at some point in the future (future : do nothing) • that would be required with reconfiguration to meet demand at some point in the future (future : proposed) The time horizon for the modelled future states should be selected with reference to the timescales for the proposed reconfiguration. iii) Models should convert activity into the required capacity setting out the number and type of staff required and the level and type of infrastructure (e.g. beds, theatres). iv) Analysis should identify those assumptions on which the modelled futures states are particularly sensitive. v) The models should clearly articulate any material implications for aligned services and sectors (e.g. repatriation of patients from specialist centres for subsequent phases of care). Evidence of agreement in principle from those other services should be provided.

	Evidence required	Further guidance on evidence required
e)	Describe and evidence the impact that proposals are expected to have on the sustainability of affected and related services (including those in other health economies)	i) Proposals should demonstrate compliance with national guidance on workforce requirements. Where proposals do not comply or involve models of care not covered by guidance, an independent assessment should be undertaken and provided. Evidence of engagement with Health Education England and the outcome of that engagement should also be provided. ii) Proposals should set out their sustainability in terms of clinical workforce by supplying, where relevant: • a workforce plan broken down by discipline, grade and site (and covering current staff levels and the alignment of future staff levels with activity projections and/or national guidelines) • clinical rotas (PAs not WTE) for all services affected including interdependent services across sites and in affected providers across primary, acute and community care • analysis of competencies/skill mix required • recruitment and retention plans (including associated training requirements) • research and innovation plans • outline plans for how any working practices/cultures will be changed, where this is required for successful implementation • Staff engagement and plans to support staff transition.
f)	Evidence of local clinical support.	i) Detail the names/roles of local clinical and patient champions for proposals. ii) Provide written evidence from local clinical leaders/groups confirming explicit support for the proposals and highlighting any remaining areas of concern to them (e.g. CCG AOs, LMC, GP Federation, relevant medical and nursing directors). CCG letters should confirm the affordability of proposals (no detailed financial information will be required by the Senate).
g)	Provide a summary of how your proposals would support each relevant domain of the outcomes framework.	This could be done in tabular form, linking to other sections as required. Where there is any potential adverse impact this should be made explicit and a summary of the proposed mitigation provided. i) Domain 1 - Preventing people from dying prematurely ii) Domain 2 - Enhancing quality of life for people with long-term conditions iii) Domain 3 - Helping people to recover from episodes of ill health or following injury iv) Domain 4 - Ensuring that people have a positive experience of care v) Domain 5 - Treating and caring for people in a safe environment and protecting them from avoidable harm

	Evidence required	Further guidance on evidence required
h)	Provide a narrative summary of how your proposals would support the rights and pledges in the NHS Constitution.	This could be done in tabular form, linking to other sections as required. Where there is any potential adverse impact this should be made explicit and a summary of the proposed mitigation provided. i) rights about access to health services ii) rights about quality of care and environment, such as the provision of same-sex hospital accommodation iii) rights about treatments and drugs- rights about consent and confidentiality iv) rights about patient choice v) rights about your own involvement in your healthcare – for example, through schemes such as personal health budgets vi) rights to complaints and redress
i)	Provide a summary of relevant local strategic needs analyses and commissioning plans and of how your proposals address those needs and complement those plans.	This could be done in tabular form, linking to other sections as required, and should include. i) Consideration of commissioning plans should include all relevant commissioners – NHSE, CCGs, local authorities (social care and public health). ii) Engagement with and explicit support from Health and Wellbeing Boards.
j)	Describe the alignment between your proposals and wider system plans (e.g. local Sustainability and Transformation Plans).	i) Evidence of engagement with other relevant providers/health economies should be included (e.g. neighbouring Trusts, ambulance services) along with the outcome of that engagement especially in relation to issues of clinical and financial sustainability. ii) If local public health/social care plans and plans of specialised commissioners are not contained in wider system plans they must be separately referenced. iii) Where proposals involve significant hospital bed closures, proposers must also demonstrate that they can meet one of three conditions: • That sufficient alternative provision, such as increased GP or community services, is being put in place alongside or ahead of bed closures, and that the new workforce will be there to deliver it; and/or • That specific new treatments or therapies, such as new anti-coagulation drugs used to treat strokes, will reduce specific categories of admissions; and/or • Where a hospital has been using beds less efficiently than the national average, that it has a credible plan to improve performance without affecting patient care (for example in line with the Getting it Right First Time programme).

	Evidence required	Further guidance on evidence required
k)	Describe how your proposals support integrated working.	i) This includes integration with other health and social care services. ii) For hospital proposals, drawings showing changes in physical adjacencies should be provided. iii) Evidence of planning related to the integration of services should set out how independent living, self-management and self-care will be promoted and supported.
l)	Set out your appraisal of the risks of implementing the proposals.	For each risk identified, summarise key mitigating actions proposed. This should include: i) The safety, effectiveness or experience of patient care ii) The deliverability of your proposals - potential adverse impacts on related/co-dependent services (including destabilisation of services) iii) Proposed physical solutions iv) The accuracy of activity, capacity and workforce projections v) Formal modelling of any impact on Emergency Preparedness, Resilience and Response (EPRR) plans with mitigation where required.
m)	Provide a summary narrative addressing Stage 1 issues/recommendations.	These could be referenced to where supporting evidence can be found in responses to other parts of the framework.
6. Option Development and Appraisal		
Show that options are affordable, clinically viable and deliverable: • *Demonstrate evaluation of options against a clear set of criteria.* • *Demonstrate affordability and value for money (including projections on income and expenditure and capital costs/receipts for affected bodies).* • *Demonstrate proposals are affordable in terms of capital investment, deliverability on site (with any outline plans), and transitional and recurrent revenue impact. It is helpful to take account of the requirements that individual providers' capital investment business cases will need to satisfy.*		
a)	Set out the range of options you have considered, including alternatives to reconfiguration.	Evidence could include: i) Detailed reports on option development and appraisal processes and outcomes (including the 'do nothing' and excluded options with rationale for exclusion/preference) ii) Describe alternative solutions/staffing models considered with rationale for exclusion (e.g. Would it be possible to achieve the same benefits through redesigned and shared rotas? Where reconfiguration involves skill-mix changes, for example shift of activities to nurse practitioners in Minor Injury Units instead of ED, has the impact on doctors' job plans been worked through?)

	Evidence required	Further guidance on evidence required
b)	Set out the expected impact of estates changes on the safety, effectiveness and experience of care.	Evidence of compliance/clarity of derogation from Health Building Notes, compliance with privacy and dignity requirements, BREEAM assessment, etc.
7. Pre Consultation Engagement		
Outline how stakeholders, patients and the public have been involved, proposed further approaches and how their views have informed options. Explain how the proposed changes impact on local government services and the response of local government.		
a)	Evidence the extent to which local clinicians and communities believe the proposals will deliver real benefits for service users and carers in the affected populations.	i) Summary of public/clinical involvement and engagement including materials used and events held. ii) Details of key current or expected challenges to proposals (including an evidenced assessment of the strength/breadth of support for challenges) and of your responses to those challenges. iii) Provide written evidence from local patient bodies confirming explicit support for the proposals and highlighting any remaining areas of concern to them (Healthwatch, groups representing affected service users/carers).
8. Impact Assessments		
• *Include an analysis of travelling times and distances.* • *Outline how the proposed service changes will promote equality, tackle health inequalities and demonstrate how the commissioners have met the Public Sector Equality Duty.* • *Summarise information governance issues identified by the privacy impact assessment.*		

	Evidence required	Further guidance on evidence required
a)	Provide modelling of the impact of your proposals on patient access, reflecting the proposed patient pathway(s).	i) Analysis should show the patient travel times and distances using road networks and drive times and, where appropriate, public transport routes and timetables. In additional to total and average (median) travel times and distances, analysis should also show the changes in the distribution of times and distances and identify geographic areas where residents travel times might be substantially altered as a result of the proposed reconfiguration. ii) The default assumption in any service modelling should be that patients will travel to their nearest suitable provider. Where different assumptions are used these should be set out, justified and the results compared to those under the default assumption. iii) Travel time analysis should where appropriate consider the implications of any service reconfiguration on families and carers, and mitigating actions should be included. iv) Evidence of impact on ambulance services and/or other affected patient transport service should be set out with confirmation of support from affected providers.
b)	Summarise the expected impact of your proposals on health inequalities including areas of direct benefit and mitigations where there is a risk of increasing disadvantage for some groups.	i) As a minimum a robust Equalities Analysis should be included. Ideally this should be submitted as part of an Integrated Impact Assessment appropriate to the pre-consultation Options stage (in line with guidance in the *Integrated Impact Assessment Toolkit*). ii) Proposals should describe the issues/concerns raised by groups with protected characteristics and how they have been/will be adapted in response. iii) Evidence of how the proposal takes into account the emerging findings of the Equalities Analysis and other impact assessments.
9. Programme Management		
• *Identify governance and decision making arrangements.* • *Identify indicative implementation timelines.* • *Independent advice should be sought to assess the programme management arrangements and the strength of the business case.*		
a)	Describe how the performance of current services will be sustained throughout the lifecycle of the reconfiguration programme	Business continuity plans, network support arrangements, assessment of the potential need for emergency measures (with details of any associated governance processes).

	Evidence required	Further guidance on evidence required
b)	Describe your outline plans for how proposals would be implemented.	This should cover i) Provision for clinical leadership for implementation ii) Plans for maintaining clinical involvement and support iii) Supporting transformation capacity and capability.