The Integrated Support and Assurance Process (ISAP): detailed guidance on assuring novel and complex contracts

Part C: Guidance for NHS trusts and NHS foundation trusts

Published by NHS England and NHS Improvement

August 2017

First published: **Friday 5 November 2016**

Revised version published: **Wednesday 16 August 2017**

Prepared by: **NHS England and NHS Improvement**

This document is for: Commissioners, NHS trusts, NHS foundation trusts and independent providers.

Publication Gateway Reference: **07096**

The current version of the document will always be made available on the NHS England website.

Version 2.0

This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages, upon request. Please contact 0300 311 22 33 or email england.contactus@nhs.net.

Contents

1. Introduction

1.1 Guidance for NHS trusts and foundation trusts

Part C of the Integrated Support and Assurance Process (ISAP) guidance applies to any NHS trust or foundation trust (called 'trusts' in this guidance) bidding for novel or complex contracts (called 'complex contracts' in this guidance). It also applies to subsidiaries and joint ventures wholly or partly owned by a trust.

This part of the guidance describes how the ISAP applies to trusts and what NHS Improvement will do at each checkpoint. The appendices provide guidance to selected bidders on how to prepare for Checkpoint 2, including a suggested structure for a full business case. While aimed at trusts, this guidance may also help independent providers.

This part of the guidance should be read in conjunction with *The Integrated Support and Assurance Process (ISAP): guidance on assuring novel and complex contracts, Part A: Introduction*.

2. Applying ISAP to NHS trusts and foundation trusts

The ISAP brings together NHS Improvement's transaction review and NHS England's approach to reviewing major service redesign.

This means that NHS Improvement will apply its existing transaction guidance to any trust that a commissioner selects as preferred bidder and which consequently enters into a complex contract. The thresholds for a review are described in Appendix 1 of NHS Improvement's transaction guidance.[1]

Trusts will be subject to NHS Improvement's transaction review process at Checkpoint 2. Under the ISAP, NHS Improvement will also have a role at Checkpoint 1 before the preferred bidder is selected and at Checkpoint 3 before the contract goes live.

2.1 Checkpoint 1

Providers will not be questioned at Checkpoint 1 as it takes place before formal procurement and before the preferred bidder is identified. NHS Improvement will not require any submissions from providers at this stage. However, it will review some of the documentation submitted by commissioners as described in *Part B: Key Lines of Enquiry*.

[1] *Supporting NHS providers: guidance on transactions for NHS foundation trusts* updated March 2015 at www.gov.uk/government/publications/supporting-nhs-providers-considering-transactions-and-mergers

It is important that the commissioner can demonstrate at Checkpoint 1 that it has completed appropriate engagement with current and potential providers before starting the procurement. In addition, NHS Improvement will contribute to NHS England's assessment of whether or not the proposed approach could be a good solution for the local health economy in the context of the relevant sustainability and transformation plan(s).

NHS Improvement will also contribute to NHS England's assessment of whether the proposed risk allocation in the contract is likely to be acceptable to any potential providers.

2.2 Checkpoint 2

At Checkpoint 2, NHS Improvement will ask of the preferred bidder (if it is a trust) the questions below. These questions are aligned with NHS Improvement's transaction guidance.

Checkpoint 2
Domain 1/4: Strategy
• Is the provider's overall strategy well-reasoned and can the board articulate how the contract supports its delivery? • Has there been a detailed options appraisal and is there a clear rationale as to why the provider has decided to bid for the new and novel contract? • Does this rationale set out why it is the best option for patients, providers and the local health economy? • Does the provider board have capability, capacity and experience to deliver? • Has the provider appropriately determined the potential nature and extent of any competition issues which may be raised by any transaction required for its delivery of the contract? • If relevant, how does the provider's completed assessment of any competition issues compare to NHS Improvement's own assessment? • If relevant, has a preliminary review of the provider's approach to assessing relevant patient benefits, robustness of plans for their realisation, and the fit with local commissioning intentions been undertaken?
Domain 2/4: Transaction execution
• Does the provider board have the appropriate capability and capacity to minimise execution risks? • Is the provider board able to identify and quantify contract risks appropriately (including any risks associated with competition rules)? Is its approach to due diligence robust and is there evidence that key risks have been recorded? • Has the provider board effectively mitigated key risks and established effective processes for the continued management of these risks following contract award?

- Is there a robust and comprehensive plan for delivery of the contract, including integration and realisation of other benefits?
- Is the implementation plan sufficiently supported by clear lines of accountability, governance processes, delivery milestones and dedicated resource?
- Has the provider met all regulatory and legal requirements (including NHS Improvement certification and licensing where relevant)?

Domain 3/4: Quality

- Has the provider received a clean quality governance opinion (where relevant)?
- Has the provider's medical director provided a certification to NHS Improvement?
- What is CQC's view of the provider and the impact of the planned contract?
- Would the organisation trigger any governance concerns under NHS Improvement's Single Oversight Framework by entering into the contract?

Domain 4/4: Financial

- Does the provider's plan demonstrate financial viability following contract award? Has the provider considered and quantified a realistic set of risk scenarios and mitigations as part of this plan?
- Has the provider received an unqualified financial reporting procedures opinion (where relevant)?
- Has the provider received an unqualified working capital opinion (where relevant)?

Checkpoint 2: Sources of evidence

Jointly developed submissions

- NHS Improvement will request a local health economy financial model as part of Checkpoint 2 submissions. This should update the financial model that the commissioner submits at Checkpoint 1. NHS Improvement expects the preferred bidder and the commissioner to develop the model jointly. It should describe the proposed new contract's impact on all relevant commissioners and providers.

Trust submissions

- The sources of evidence for trusts include those in NHS Improvement's transactions guidance. This includes, but is not limited to:
    - Full business case (see Appendix 2 for guidance on preparing a full business case);
    - Provider financial model;
    - Self-certifications; and
    - Management representation letter to confirm all relevant information has been disclosed to NHS Improvement.

- Unqualified independent accountant opinions *may* be required for:
    - Financial reporting procedures;
    - Working capital;
    - Quality governance; and
    - Post-transaction integration planning.

  NHS Improvement will take a proportionate and risk-based approach to the requirement to submit these opinions. Trusts should discuss and agree with NHS Improvement its plans for obtaining these opinions before procuring independent accounting firms.

At the end of Checkpoint 2, NHS Improvement will issue a final risk rating to the trust in line with its transaction guidance. NHS Improvement will expect trusts to pause and adapt their involvement in a transaction if it issues a red transaction risk rating.

Appendix 1 provides guidance to trusts on how to streamline Checkpoint 2 as much as possible, including how to minimise time spent preparing submissions.

2.3 Checkpoint 3

At Checkpoint 3, NHS Improvement will request a letter from trust management describing significant changes (if any) that have occurred since completion of Checkpoint 2. It will also request details of how any recommendations and risk-rating conditions from Checkpoint 2 have been addressed.

Appendix 1: A streamlined approach to NHS Improvement's transaction reviews as part of Checkpoint 2

1. Introduction

After the procurement process, the commissioner will select its preferred provider. If this provider is an NHS trust or foundation trust, it will be subject to NHS Improvement's transaction review as part of Checkpoint 2. The time taken to complete this part of ISAP divides into two:

- **Document preparation phase** – when the trust prepares the submissions for the review; and
- **NHS Improvement's transaction review** – a process of up to three months, reflecting the usual timescale to review a significant transaction. This review begins once all submissions from the trust have been received.

To streamline Checkpoint 2, NHS Improvement will help trusts minimise the time taken to prepare submissions and make the transaction review as efficient as possible.

The selected trust can continue to develop proposals for contract implementation while NHS Improvement's transaction review is underway. Although an NHS Improvement risk rating is required before the contract is signed, the transaction review itself does not require the contract or implementation timetable to be 'paused'. The review can run in parallel with the commissioner's and preferred bidder's preparations. If NHS Improvement identifies material risks during its review, it will tell the selected trust as soon as possible.

2. Document preparation phase

Where possible, NHS Improvement will align information requests with those required for the commissioner's procurement process.

The level of information the commissioner requires as part of the procurement will determine the time taken to move from a bid to a full business case. Where more information is required as part of the bid (either by the commissioner or provider board), it should take less time to move to a full business case.

2.1 Timing of due diligence and business case production

Trust boards are likely to undertake due diligence to supplement the information provided during the procurement and better understand the risks they will take on as part of the contract. The timing of the due diligence will affect how long it takes from selecting the preferred bidder to submitting the full business case. In certain

circumstances (for example, where the time to mobilisation is a critical factor, or the number of bidders is limited), a trust may decide to invest in more due diligence during the bidding phase to minimise the time between a bid and a full business case. This allows the trust to make a more informed bid, although it must be judged against the cost of investment.

Similarly, a trust may wish to start preparing the full business case before a preferred bidder is selected so it can move more swiftly to the transaction review. This will be a matter of judgement for the trust as there is a risk it may be unsuccessful in the procurement.

3. NHS Improvement's transaction review

3.1 Guidance on preparing high quality submissions

For guidance on a suggested structure for the full business case, see Appendix 2. This will help trusts prepare the high quality submissions needed for an efficient transaction review. Any business case should, however, be designed to meet the requirements of the bidders' boards.

In preparing the full business case, trusts must consider and quantify realistic risk scenarios to evaluate the impact of the key risks they face. For a generic list of risk scenarios, see Appendix 3. Trusts will be expected to consider this list and identify risks relevant to their model. This includes considering and quantifying all other significant risks specific to their proposal, site and/or contract. NHS Improvement will update the generic scenarios based on learning from reviews and risks emerging across the NHS.

3.2 Tailoring the scope of work

Before the trust makes its Checkpoint 2 submissions, NHS Improvement will meet the organisation. This is to understand the information that already exists, agree information requirements (including the need for independent accountant opinions) and identify opportunities for making the transaction review as efficient as possible.

Appendix 2: Full business case outline

The full business case should:

Strategic rationale
• Detail the rationale for the complex contract, including how it supports the trust's strategy; • Detail the current challenges the trust and/or system faces that the complex contract seeks to address; • Detail the opportunities the complex contract represents; • Detail the synergies and benefits associated with the complex contract, including the health and wellbeing benefits, how the three gaps described in the Five Year Forward View will be addressed, the financial benefits and the impact on workforce; • Include an options appraisal, e.g.analysis of relevant patient benefits and how the organisational form of the entity holding the contract was chosen; • If the trust is working with partners to deliver the complex contract, detail how they were selected, what due diligence has been performed on them and any subcontracting arrangements; and • Detail the clinical and financial incremental benefit when compared to the counterfactual (a reasonable alternative scenario).
Transaction execution
• Identify key risks to the post-implementation strategy; • Clarify major action and contingency plans to mitigate key financial and non-financial risks; • Detail the level of consultation and engagement with key stakeholders, including feedback and how it has been incorporated into proposals; • Detail continuing stakeholder engagement; • Explain the level of support for the complex contract in the system; • Highlight major post-transaction changes to the property portfolio, with particular emphasis on property relevant to providing commissioner requested services; • Summarise key themes of any due diligence carried out for the complex contract; and • Summarise planned delivery of the proposed complex contract, including proposed timeline.
Quality
• Identify the impact of patient choice on the activity assumptions; and • Demonstrate continued provision of commissioner requested services for all patients currently receiving them, or detail and explain the rationale for

significant post-implementation changes to be made.
Finance
• Detail the financial plan, identifying key assumptions underlying projections and their relationship to the local health economy – include funding sources, risk scenarios and mitigations; and • Describe how any restructuring costs (including treatment of accumulated deficits or debts) will be handled, and how they will be funded.

Business case content

The content of the full business case will depend on the planned changes to the care model and the legal form of the entity that holds the complex contract (e.g. newly formed joint venture versus a well-established trust). **The template below is designed to help organisations prepare a business case, but trusts should adapt it to their own circumstances. It is designed as a helpful, illustrative guide and is not mandated.**

The business case should be easy to read. Where information is available in another document (e.g. the bid documents) it is acceptable to cross-refer clearly to the specific section of this document rather than redraft the information in the business case. Trusts should submit any such documents alongside the business case.

The business case should be concise, ideally not exceeding 100 pages, with a summary of about five pages. Each section should be between five and 10 pages long.

Example contents table

1. Summary

- The summary should briefly cover the business plan's key elements. It should give the reader a high level overview of the challenges facing the local health economy, how the provider plans to address them and oversee the planned changes.
- Link this section to the detailed sections later in the plan.

2. Strategic context and case for change

- A summary of the case for change from the trust's bidding documentation including an outline of how the contract supports the providers overall strategy.
- An overview of the organisation's current position in the local health economy and the challenges facing the local health economy. This may include information on population, activity and acuity projections, constraints on capacity and the associated financial impact.

- The strategic rationale for the complex contract, setting out what needs to change and why, the provider's objectives resulting from the contract, how it will address local and national policy issues and how it aligns with sustainability and transformation plans. This should also cover how it fits with the provider's own strategic vision. If trusts bid for the contract with partners, the rationale for this should be included.
- Clear explanation of the clinical and financial incremental benefit compared to a reasonable alternative scenario (the counterfactual – unlikely to be a do-nothing scenario but one where changes are implemented under the current structure and payment mechanism). This should describe what is already being done, how the trust will build on it and why these incremental changes can only be achieved through the proposed structures (or why it is the preferred way to implement the changes).
- Options appraisal: an overview of why the trust decided to bid for the complex contract and what alternatives it considered. This section should include a brief summary of the alternative solutions/models considered and why this particular option was selected, as well as patient benefits.
- Stakeholder engagement: detail the level of consultation and engagement with key stakeholders (by the CCG and/or trust), including feedback and how it was incorporated into proposals as well as plans for continuing stakeholder engagement during the life of the contract.

3. Clinical strategy

3.1 Overview

- Overview of planned changes to the service model and how they will improve care for the local population. This should cover when the changes will take place.
- It should be clear how patient care will be delivered differently and how this will feel different for patients. This should be supported by, or cross-refer to, case studies or patient journey scenarios.
- The assumed benefits of these changes (e.g health and wellbeing, patient experience, outcomes, activity reduction, cost reduction) should be clearly described and supported by local, national or international evidence.

3.2 Population needs

- Summarising how the local population's health needs were analysed, identifying critical patient cohorts and how this led to the planned changes to clinical pathways, as well as the key enablers for the planned changes.
- Detail how the clinical model ensures the continued provision of commissioner requested services for patients.
- Description of how the care model's impact on competition was assessed, and where issues are identified, how these have been mitigated.

3.3 Enablers

- Enablers are likely to include information management and technology (IM&T). The business case should include an overview of the planned IM&T changes and the information governance implications. If included in a separate chapter, cross-refer to this in the clinical strategy.
- Explain any workforce implications (or cross-refer to a separate chapter). This should cover how primary, secondary and/or social care will be delivered differently and in a more integrated way, where the skills gaps are and the plans to address them.

4. Financial plans

4.1 Summary

- For the entity holding the contract: a financial summary showing the contract value (including any outcome-based incentive payments), transaction / transformation/transition costs, source of any planned funding, working capital, savings challenge by year and the base financial case, linked to control totals. The assumptions used in the base case, and the rationale for them, should be clearly described and linked to the planned clinical and workforce changes.
- If the trust writing the business case does not directly hold the contract (e.g. it is held by a joint venture or the trust is a subcontractor), a separate financial section should be included describing the contract's impact on the trust's financial viability.
- Overview of the planned cost improvements within the trust itself and the planned incremental savings resulting from the complex contract, the individuals responsible for delivery and how the impact on quality has been assessed. The planned savings should, as far as possible, be evidence-based and calculated on a bottom-up basis. Where possible, local evidence should be used – for example, building on local pilots of the new ways of working. This section should also include details for any planned estate and back-office rationalisation.
- In addition to the information in the business case, trusts will be required to complete NHS Improvement's long-term financial model and submit this alongside the business case.

4.2 Financial risks and mitigations

- This section should also include information on a mitigated downside scenario. See Appendix 3 for further guidance on financial risks that should be considered as part of the downside planning. This should be a reasonable downside scenario and mitigations should undergo a similar level of scrutiny to cost improvement plans (e.g. staff engagement, quality impact assessment).

5. Risks and mitigations

- An overview of the due diligence carried out, key risks arising from the complex contract, how these were identified and how they will be mitigated and monitored. This should include any due diligence carried out on the trust's partners and/or subcontractors for the complex contract.
- Where the contract is not held directly by the trust, a distinction between trust and other risks should be made.

6. Leadership and workforce

- An overview of the board's skills and experience to oversee the planned changes (e.g. change management, commissioning, contracting, new services) and how identified skills gaps have been/will be addressed. Cross-refer to an appendix of pen portraits.
- Recognising that it will take significant leadership time to plan for and implement the changes, describe the steps taken to create additional senior management capacity.
- If not covered in the clinical strategy section, an overview of the new ways of working under the revised clinical model and the associated workforce implications. This should be supported by a workforce model detailing workforce implications by staff group, grade and location. Detail plans to address staff shortages, skills gaps and training for new roles.
- The level of staff commitment to and engagement with the planned changes (e.g. involvement in designing clinical pathway changes). This should include staff affected across the system, not just staff within the entity holding the contract.
- Details of further additional resource required to implement the complex contract. For example, the size and role of a project management office (PMO) and whether it has been created internally or is externally resourced. The associated cost and source of funding should be clearly described.

7. Commercial terms

- Explain the legal form of the entity or entities that will hold the contract (e.g. the trust itself/corporate joint venture/contractual joint venture). If it is held by a joint venture, describe who the parties to the joint venture are, their level of ownership, voting and decision-making arrangements and other key terms of the joint venture agreement.
- Overview of the various legal agreements required as part of the contracting (e.g. head contract with commissioner, joint venture agreement, risk-share agreement, subcontracts, business transfer agreement) and the timeline for finalising these agreements.
- A summary of any legal due diligence undertaken.

- Describe the key terms of the head contract (e.g. scope of services, value, outcome-based incentive payments, length of contract, break clauses, risk/gain share arrangements) and the key areas still under negotiation. Make it clear if any areas under negotiation represent a red line for the board (e.g. risk share, nature of outcome-based incentive payments).
- A summary of the key partners or subcontractors and the status of negotiations. This should describe any risk/gain share agreements and how they differ by partner and/or subcontractor (if applicable). Clarify whether existing contracts will novate as part of the transaction or if new contracts are being negotiated. Provide an overview of the process by which the provider will decide who it is going to subcontract with in future years.
- For the outcome-based element of the contract, include analysis of the likelihood of achieving payment and link these outcomes to the assumed benefits of the new service model.

8. Governance arrangements

- Overview of the agreed governance arrangements for managing the complex contract across organisations, including risk management, reporting (financial, operational and clinical) and decision-making processes and mechanisms.
- Overview of clinical governance arrangements describing how the contract holder is assured about clinical performance in subcontractors and which organisation is accountable for clinical risk.
- Where there is a transition phase for these governance arrangements, clearly describe the governance arrangements for the mobilisation phase, immediately after go-live and the final planned arrangements.
- Describe the proposed governance structure for managing the new contract, including membership, terms of reference and members' voting rights. Where there is multiparty representation on the committee or board, the business case (or supporting documents) should describe how the board or committee will take decisions, whether these decisions are binding on the respective bodies and how conflicts will be managed.
- This section should include scenarios describing how complex and contentious decisions will be taken and how potential conflicts of interest will be addressed. All relevant parties should understand these principles in advance of a go-live date.
- A summary of how all subcontractors and partners will be held to account for service change and delivery, and how the risk associated with potential provider failure will be managed.
- An overview of how local stakeholders' views will be considered (eg membership on the committee).

9. Mobilisation and implementation

- An overview of the mobilisation phases between Checkpoint 2 and go-live after Checkpoint 3. This should include key milestones, anticipated challenges and how the process with be governed. This should also cover TUPE arrangements if applicable.
- An overview of the post go-live implementation plans. This should describe the phases and key milestones for the planned changes and the associated timelines.
- This should include how the PMO will support these processes.
- Include a summary of the benefits realisation plan and how it will be measured and reported.
- This chapter should be supported by a post-contract award delivery plan and benefits realisation plan.

10. Appendices

Appendix 3: Example risk scenarios

In preparing the full business case for NHS Improvement's transaction review at Checkpoint 2, trusts will be required to consider and quantify a realistic, comprehensive set of risk scenarios to evaluate the impact of the key risks they face. A 'generic' list of risk scenarios is below. However, NHS Improvement expects trusts to have considered whether these apply.

In addition to this 'generic' list, trusts will be expected to include consideration and quantification of all other significant risks that are specific to their site and/or contract.

Risk themes		Risks	Examples
New care model	1.	Activity and acuity	*Greater activity growth and/or acuity than planned* *Lower demand management achieved* *Unsuccessful activity redirection*
	2.	Incremental savings	*Lower cost savings than planned, e.g. due to insufficient evidence or optimism bias* *Implications of provider form, e.g. VAT*
	3.	Phasing	*Delays in implementing new service model* *Delays in realising net benefits*
	4.	Workforce	*Insufficient workforce engagement* *Lack of detailed workforce plan to underpin the new service delivery model*
	5.	Unexpected transitional or capital funding requirements	*Lack of community infrastructure* *IT enablers* *PMO/NMC project team costs* *Double running costs*
Contract	6.	Clarity on cost and scope of services	*Contract financial envelope less than the cost of providing the services, e.g. due to:* • *lack of transparency on existing costs* • *scope of services to be*

			provided not fully defined at the outset • *contract variations not fully defined and agreed*
	7.	Baseline adjustments	*Lower system allocations*
	8.	Outcome-based contract elements	*Non-delivery of outcomes* *Poorly defined outcomes measures that are difficult to evidence*
	9.	Risk sharing	*Application of risk-sharing mechanisms*
Business-as-usual	10.	Unexpected stranded costs	*Changes in workforce composition* *Fixed-term outsourcing contracts*
	11.	Under-delivery of other BAU CIPs	*Double counting of BAU CIPs and CIPs associated with new care models*